NICORETTE ICE MINT 2 and 4 MG GUM
NICORETTE SPEARMINT 2 and 4 MG GUM

PL  15513/0143-4
PL  15513/0152-3

UKPAR

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The Medicines and Healthcare products Regulatory Agency granted Pfizer Consumer Health Care Marketing Authorisations (licences) for the medicinal products Nicorette Ice Mint 2 and 4 mg Gum (PL 15513/0143-4) and Nicorette Spearmint 2 and 4 mg Gum (PL 15513/0152-3) on 18 July 2006. These products have been granted a general sale licence (GSL), which means that they are available without prescription and do not have to be bought under supervision of a pharmacist.

Nicotine, containing gum similar to these products has been available in the European Union, including the UK, for more than ten years. Their use is well established with recognised efficacy and acceptable safety.

Nicorette Ice Mint and Spearmint 2 and 4 mg Gum raised no clinically significant safety concerns and it was therefore judged that the benefits of using these products outweigh the risks; hence Marketing Authorisations have been granted.
NICORETTE ICE MINT 2 and 4 MG GUM
NICORETTE SPEARMINT 2 and 4 MG GUM

PL 15513/0143-4
PL 15513/0152-3

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy the UK granted marketing authorisations for the medicinal products, Nicorette Ice Mint 2 and 4 mg Gum (PL 15513/0143-4) and Nicorette Spearmint 2 and 4 mg Gum (PL 15513/0152-3) to Pfizer Consumer Health Care. These products hold a GSL.

These national applications for Nicorette Ice Mint and Spearmint 2 and 4 mg Gum are submitted under EC, Article 10.1 of Directive 2001/83/EC.

Nicorette gum contains the active ingredient nicotine resinate and is indicated for the relief of nicotine withdrawal symptoms as an aid to smoking cessation.
PHARMACEUTICAL ASSESSMENT

INTRODUCTION
These are simple national abridged Marketing Authorisation applications for Nicorette Ice Mint 2mg Gum and 4mg Gum (PL 15513/0143-4); and Nicorette Spearmint 2mg Gum and 4mg Gum (PL 15513/0152-3), cross-referring to existing products on the UK market: Nicorette Freshmint 2mg Gum and 4mg Gum (PL 00032/0283 and 00032/0295), granted to Pharmacia on 31 July 2000 and 1 May 2001, respectively.

A letter has been provided confirming a change of ownership of all Pharmacia Limited Consumer Healthcare Products to Pfizer Consumer Health. Letters of access from Pharmacia referring to the Ice Mint products and the Spearmint products are provided in favour of the applicant.

EXPERT REPORTS
Expert statements, along with CVs that confirm they are suitably qualified, are provided by the quality, non-clinical and clinical experts, indicating that the proposed product is similar to the cross-reference product. These statements are acceptable.

MAA FORMS
Details provided are generally identical to those of the cross-referral licence.

SUMMARY OF PRODUCT CHARACTERISTICS
SPCs are identical to those of the cross-reference products, apart from updates bringing them in line with current guidelines.

ADDITIONAL DATA REQUIREMENTS
Details provided are generally identical to those of the cross-referral licence.

TSE
Confirmation is given in annex 6.12 that none of the components are of animal origin.

LABELLING
Colour mock-ups of the final labels have been provided.
All labelling is satisfactory.

LEAFLET
The leaflet reflects the SPC and is satisfactory.
Colour mock-ups of the final leaflet have been provided.

PHARMACEUTICAL CONCLUSIONS
Market Authorisation should be granted for these products.
PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type.
CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for an application of this type.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The data for these applications are consistent with that previously assessed for the cross-reference products and, as such, have been judged to be satisfactory.

PRECLINICAL
No new preclinical data were submitted and none are required for applications of this type.

EFFICACY
No new or unexpected safety concerns arise from these applications.

The SPC, PIL and labelling are satisfactory and consistent with that for the cross-reference products.

RISK BENEFIT ASSESSMENT
The quality of the products is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant’s products are identical to the cross-reference products. The risk benefit ratio is considered to be positive.
### STEPS TAKEN FOR ASSESSMENT

<table>
<thead>
<tr>
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<th>Description</th>
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<tr>
<td>1</td>
<td>The MHRA received the marketing authorisation application on 11 February 2005</td>
</tr>
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<td>2</td>
<td>Following assessment of the application, the MHRA requested further information relating to the quality dossier on 20 April and 22 June 2005</td>
</tr>
<tr>
<td>3</td>
<td>The applicant responded to the MHRA’s requests, providing further information on 16 January 2006</td>
</tr>
<tr>
<td>4</td>
<td>The application was determined on 18 July 2006</td>
</tr>
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</table>
UKPAR Nicorette Ice Mint and Spearmint 2 and 4 mg Gum (PL 15513/0143-4 & 152-3)

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
Nicorette Ice Mint 2mg Gum

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Chewing Gum containing 2mg nicotine, as nicotine resinate.

For excipients, see 6.1.

3. PHARMACEUTICAL FORM
Medicated Chewing Gum

A square, coated, white coloured piece of gum

4. CLINICAL PARTICULARS
4.1. Therapeutic indications
Nicorette Ice Mint 2mg Gum is for the relief of nicotine withdrawal symptoms as an aid to smoking cessation in adults and children over 12 years of age. It is also indicated in pregnant and lactating women (see section 4.6).

In smokers currently unable or not ready to stop smoking abruptly, the gum may also be used as part of a programme to reduce smoking prior to stopping completely.

If possible, Nicorette Ice Mint 2mg Gum should be used in conjunction with a behavioural support programme.

4.2. Posology and method of administration
Nicorette Ice Mint 2mg Gum should be chewed slowly according to the instructions.

The strength of gum to be used will depend on the smoking habits of the individual. In general, if the patient smokes 20 or less cigarettes a day, 2mg nicotine gum is indicated. If more that 20 cigarettes per day are smoked, 4mg nicotine gum will be needed to meet the withdrawal of the high serum nicotine levels from heavy smoking.

The chewing gums should be used whenever there is an urge to smoke according to the “chew and rest” technique described on the pack. After about 30 minutes of such use, the gum will be exhausted. Not more than 15 pieces of the chewing gum may be used each day. Absorption of nicotine is through the buccal mucosa, any nicotine which is swallowed being destroyed by the liver.

Behavioural therapy, advice and support will normally improve the success rate.

Smoking cessation
Adults (over 18 years of age)
The patient should make every effort to stop smoking completely during treatment with Nicorette Ice Mint 2mg Gum.

Use the gum whenever there is an urge to smoke to maintain complete abstinence from smoking. Sufficient gums should be used, usually 8-12, up to a maximum of 15.

Continue use for up to three months to break the habit of smoking, and then gradually reduce gum use. When daily use is 1-2 gums, use should be stopped.

For those using 4 mg nicotine gum, the 2 mg nicotine gum will be helpful during withdrawal from treatment.

Any spare gum should be retained, as craving may suddenly return.
Adults who use NRT beyond 9 months for smoking cessation are recommended to seek additional help and advice from a healthcare professional.

**Adolescents (12 to 18 years)**

The patient should make every effort to stop smoking completely during treatment with Nicorette Ice Mint 2mg Gum.

Use the gum whenever there is an urge to smoke to maintain complete abstinence from smoking. Sufficient gums should be used, usually 8-12, up to a maximum of 15.

Continue use for up to 8 weeks to break the habit of smoking, then gradually reduce gum use over a 4 week period. When daily use is 1-2 gums, use should be stopped.

For those using 4 mg nicotine gum, the 2 mg nicotine gum will be helpful during withdrawal from treatment.

As data are limited in this age group, the recommended duration of treatment is 12 weeks. If longer treatment is required, advice from a healthcare professional should be sought.

**Smoking reduction**

**Adults (over 18 years of age)**

Use the gum between smoking episodes to manage the urge to smoke, to prolong smoke-free intervals and with the intention to reduce smoking as much as possible. If a reduction in number of cigarettes per day has not been achieved after 6 weeks, professional advice should be sought.

A quit attempt should be made as soon as the smoker feels ready, but not later than 6 months after start of treatment. If a quit attempt cannot be made within 9 months after starting treatment, professional advice should be sought.

When making a quit attempt the smoking cessation instructions above can be followed.

**Adolescents (12 to 18 years)**

Where adolescents are motivated to stop smoking abruptly, smoking cessation should be recommended. However, smoking reduction can be considered where adolescents are not ready or able to stop smoking abruptly. As data are limited in this age group, and the recommended duration of NRT is 12 weeks, adolescents should consult a healthcare professional before starting the “smoking reduction prior to stopping” regimen.

Use the gum between smoking episodes to manage the urge to smoke, to prolong smoke-free intervals and with the intention to reduce smoking as much as possible. If a reduction in number of cigarettes per day has not been achieved after 6 weeks, professional advice should be sought.

A quit attempt should be made as soon as the smoker feels ready, but not later than 6 months after start of treatment. If a quit attempt cannot be made within 9 months after starting treatment, professional advice should be sought.

When making a quit attempt the smoking cessation instructions for adolescents (12 to 18 years) given above can be followed.

**4.3. Contraindications**

Hypersensitivity to nicotine or any component of the chewing gum.

**4.4. Special warnings and precautions for use**

Any risks that may be associated with NRT are substantially outweighed by the well established dangers of continued smoking.

*Underlying cardiovascular disease:* In stable cardiovascular disease Nicorette Ice Mint 2mg Gum presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction, severe dysrhythmia or CVA and
who are considered to be haemodynamically unstable should be encouraged to stop smoking with non-pharmacological interventions. If this fails, Nicorette Ice Mint 2mg Gum may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision.

Diabetes mellitus: Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when NRT is initiated as catecholamines released by nicotine can affect carbohydrate metabolism.

GI disease: Swallowed nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastritis or peptic ulcers and oral NRT preparations should be used with caution in these conditions. Ulcerative stomatitis has been reported.

Renal or hepatic impairment: Nicorette Ice Mint 2mg Gum should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

Danger in small children: Doses of nicotine tolerated by adult and adolescent smokers can produce severe toxicity in small children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children. Nicotine gum should be disposed of with care.

Phaeochromocytoma and uncontrolled hyperthyroidism: As nicotine causes release of catecholamines, Nicorette Ice Mint 2mg Gum should be used with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma.

Transferred dependence: Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

Stopping smoking: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole.

Excipients: Nicorette Ice Mint 2mg Gum also contains butylated hydroxy toluene (E321); this may cause irritation to the mucous membranes.

Denture warning: Smokers who wear dentures may experience difficulty in chewing Nicorette Ice Mint 2mg Gum. The chewing gum may stick to, and may in rare cases damage dentures.

4.5. Interactions with other medicinal products and other forms of interaction
No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

4.6. Pregnancy and lactation
Pregnancy
NRT is not contraindicated in pregnancy. The decision to use NRT should be made on a risk-benefit assessment as early on in the pregnancy as possible with the aim of discontinuing use as soon as possible.

Smoking during pregnancy is associated with risks such as intra-uterine growth retardation, premature birth or stillbirth. Stopping smoking is the single most effective intervention for improving the health of both pregnant smoker and her baby. The earlier abstinence is achieved the better.
Ideally smoking cessation during pregnancy should be achieved without NRT. However for women unable to quit on their own, NRT may be recommended to assist a quit attempt.

Nicotine passes to the fetus affecting breathing movements and has a dose-dependent effect on placental/fetal circulation. However the risk of using NRT to the fetus is lower than that expected with tobacco smoking, due to lower maximal plasma nicotine concentration and no additional exposure to polycyclic hydrocarbons and carbon monoxide.

Intermittent dosing products may be preferable as these usually provide a lower daily dose of nicotine than patches. However, patches may be preferred if the woman is suffering from nausea during pregnancy. If patches are used they should be removed before going to bed.

Lactation

NRT is not contraindicated in lactation. Nicotine from smoking and NRT is found in breast milk. However the amount of nicotine the infant is exposed to is relatively small and less hazardous than the second-hand smoke they would otherwise be exposed to.

Using intermittent dose NRT preparations, compared with patches, may minimize the amount of nicotine in the breast milk as the time between administrations of NRT and feeding can be more easily prolonged.

4.7. Effects on ability to drive and use machines

Not applicable.

4.8. Undesirable effects

Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include; irritability/aggression, dysphoria/depressed mood, anxiety, restlessness, poor concentration, increased appetite/weight gain, urges to smoke (cravings), night-time awakenings/sleep disturbance and decreased heart rate.

Increased frequency of aphthous ulcer may occur after abstinence from smoking. The causality is unclear.

Nicorette Ice Mint 2mg Gum may cause adverse reactions similar to those associated with nicotine given by other means, including smoking, and these are mainly dose-dependent. At recommended doses Nicorette Ice Mint 2mg Gum has not been found to cause any serious adverse effects. Most of the undesirable effects reported by the patients occur during the first 3-4 weeks after start of treatment.

Excessive consumption of Nicorette Ice Mint 2mg Gum by those who have not been in the habit of inhaling tobacco smoke could possibly lead to nausea, faintness or headaches. Excessive swallowing of dissolved nicotine may, at first, cause hiccupping.

Nicotine from the gum may sometimes cause a slight irritation of the throat at the start of treatment and may also cause increased salivation.

Those who are prone to indigestion may suffer initially from minor degrees of indigestion or heartburn if the 4mg nicotine gum is used; slower chewing and the use of the 2mg nicotine gum (if necessary more frequently) will usually overcome this problem.

The chewing gum may stick to, and may in rare cases damage dentures.

Reported adverse events associated with Nicorette 2mg and 4mg gum include:

<table>
<thead>
<tr>
<th>Body System</th>
<th>Incidence*</th>
<th>Reported adverse event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nervous system disorders:</td>
<td>Very common:</td>
<td>Headache</td>
</tr>
<tr>
<td></td>
<td>Common:</td>
<td>Dizziness</td>
</tr>
<tr>
<td>Cardiac disorders:</td>
<td>Uncommon:</td>
<td>Palpitations</td>
</tr>
<tr>
<td></td>
<td>Very rare:</td>
<td>Reversible atrial fibrillation</td>
</tr>
</tbody>
</table>
**Body System**  
**Gastrointestinal disorders:**  
*Very common:* Gastrointestinal discomfort, hiccups, nausea  
*Common:* Vomiting  
**Skin and subcutaneous tissue disorders:**  
*Uncommon:* Erythema, urticaria  
**General disorders and administration site conditions:**  
*Very common:* Sore mouth or throat, jaw-muscle ache  
*Rare:* Allergic reactions including angioedema

* Very common (>1/10); common (>1/100, <1/10); uncommon (>1/1000, <1/100); rare (>1/10 000, <1/1000); very rare (<1/10 000), including isolated reports.

### 4.9. Overdose

**Symptoms:** The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60mg. Symptoms of acute nicotine poisoning include nausea, salivation, abdominal pain, diarrhea, sweating, headache, dizziness, disturbed hearing and marked weakness. In extreme cases, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and terminal convulsions.

**Management of an overdose:** All nicotine intake should stop immediately and the patient should be treated symptomatically. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

### 5. PHARMACOLOGICAL PROPERTIES

#### 5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Drugs used in nicotine dependence  
ATC code: N07B A01

The pharmacological effects of nicotine are well documented. Those resulting from chewing Nicorette Ice Mint 2mg Gum are comparatively small. The response at any one time represents a summation of stimulant and depressant actions from direct, reflex and chemical mediator influences on several organs. The main pharmacological actions are central stimulation and/or depression; transient hyperpnoea; peripheral vasoconstriction (usually associated with a rise in systolic pressure); suppression of appetite and stimulation of peristalsis.

#### 5.2. Pharmacokinetic properties

Nicotine administered in chewing gums is readily absorbed from the buccal mucous membranes. Demonstrable blood levels are obtained within 5 – 7 minutes and reach a maximum about 30 minutes after the start of chewing. Blood levels are roughly proportional to the amount of nicotine chewed and have been shown never to exceed those obtained from smoking cigarettes.

#### 5.3. Preclinical safety data

Preclinical data indicate that nicotine is neither mutagenic nor genotoxic. There are no other findings derived from preclinical testing of relevance to the prescriber in determining the safety of the product which have not been considered in other relevant sections of this Summary of Product Characteristics.

### 6. PHARMACEUTICAL PARTICULARS

#### 6.1. List of excipients

<table>
<thead>
<tr>
<th>Excipient</th>
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<tbody>
<tr>
<td><strong>Core Gum</strong></td>
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<tr>
<td>Polacrilin</td>
</tr>
<tr>
<td>Chewing gum base, containing butylated hydroxy toluene (E321)</td>
</tr>
<tr>
<td>Xylitol</td>
</tr>
<tr>
<td>Peppermint oil</td>
</tr>
<tr>
<td>Sodium carbonate, anhydrous</td>
</tr>
<tr>
<td>Sodium hydrogen carbonate</td>
</tr>
<tr>
<td>Acesulfame Potassium</td>
</tr>
</tbody>
</table>

**MHRA PAR**  
14
Levomenthol
Magnesium oxide, light
Talc
Coating
Xylitol
Peppermint oil
Acacia
Titanium dioxide (E171)
Carnauba wax

6.2. **Incompatibilities**
Not applicable.

6.3. **Shelf life**
2 Years

6.4. **Special precautions for storage**
Do not store above 25°C

6.5. **Nature and contents of container**
PVC/PVDC/Al Blister packed strips each containing 15 pieces supplied in packs of 15, 30, 105 and 210 pieces.
Blister packed strips each containing 6 pieces supplied in packs of 12 pieces.
Not all pack sizes may be marketed.

6.6. **Instruction for use and handling (, and disposal)**
See section 4.2

7. **MARKETING AUTHORISATION HOLDER**
Pfizer Consumer Healthcare
Walton Oaks
Dorking Road
Walton-on-the -Hill
Surrey
KT20 7NS

8. **MARKETING AUTHORISATION NUMBER**
PL 15513/0143

9. **DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**
18/07/2006

10. **DATE OF REVISION OF THE TEXT**
18/07/2006
1. NAME OF THE MEDICINAL PRODUCT
Nicorette Ice Mint 4 mg Gum

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Chewing Gum containing 4mg nicotine, as nicotine resinate.

For excipients, see 6.1.

3. PHARMACEUTICAL FORM
Medicated Chewing Gum

A square, coated, crème coloured piece of gum

4. CLINICAL PARTICULARS
4.1. Therapeutic indications
Nicorette Ice Mint 4 mg Gum is for the relief of nicotine withdrawal symptoms as an aid to smoking cessation in adults and children over 12 years of age. It is also indicated in pregnant and lactating women (see section 4.6).

In smokers currently unable or not ready to stop smoking abruptly, the gum may also be used as part of a programme to reduce smoking prior to stopping completely.

If possible, Nicorette Ice Mint 4 mg Gum should be used in conjunction with a behavioural support programme.

4.2. Posology and method of administration
Nicorette Ice Mint 4 mg Gum should be chewed slowly according to the instructions.

The strength of gum to be used will depend on the smoking habits of the individual. In general, if the patient smokes 20 or less cigarettes a day, 2mg nicotine gum is indicated. If more that 20 cigarettes per day are smoked, 4mg nicotine gum will be needed to meet the withdrawal of the high serum nicotine levels from heavy smoking.

The chewing gums should be used whenever there is an urge to smoke according to the “chew and rest” technique described on the pack. After about 30 minutes of such use, the gum will be exhausted. Not more than 15 pieces of the chewing gum may be used each day.
Absorption of nicotine is through the buccal mucosa, any nicotine which is swallowed being destroyed by the liver.

Behavioural therapy, advice and support will normally improve the success rate.

Smoking cessation
Adults (over 18 years of age)
The patient should make every effort to stop smoking completely during treatment with Nicorette Ice Mint 4 mg Gum.

Use the gum whenever there is an urge to smoke to maintain complete abstinence from smoking. Sufficient gums should be used, usually 8-12, up to a maximum of 15.

Continue use for up to three months to break the habit of smoking, and then gradually reduce gum use. When daily use is 1-2 gums, use should be stopped.

For those using 4 mg nicotine gum, the 2 mg nicotine gum will be helpful during withdrawal from treatment.

Any spare gum should be retained, as craving may suddenly return.
Adults who use NRT beyond 9 months for smoking cessation are recommended to seek additional help and advice from a healthcare professional.
Adolescents (12 to 18 years)

The patient should make every effort to stop smoking completely during treatment with Nicorette Ice Mint 4 mg Gum.

Use the gum whenever there is an urge to smoke to maintain complete abstinence from smoking. Sufficient gums should be used, usually 8-12, up to a maximum of 15.

Continue use for up to 8 weeks to break the habit of smoking, then gradually reduce gum use over a 4 week period. When daily use is 1-2 gums, use should be stopped. For those using 4 mg nicotine gum, the 2 mg nicotine gum will be helpful during withdrawal from treatment.

As data are limited in this age group, the recommended duration of treatment is 12 weeks. If longer treatment is required, advice from a healthcare professional should be sought.

Smoking reduction

Adults (over 18 years of age)

Use the gum between smoking episodes to manage the urge to smoke, to prolong smoke-free intervals and with the intention to reduce smoking as much as possible. If a reduction in number of cigarettes per day has not been achieved after 6 weeks, professional advice should be sought.

A quit attempt should be made as soon as the smoker feels ready, but not later than 6 months after start of treatment. If a quit attempt cannot be made within 9 months after starting treatment, professional advice should be sought.

When making a quit attempt the smoking cessation instructions above can be followed.

Adolescents (12 to 18 years)

Where adolescents are motivated to stop smoking abruptly, smoking cessation should be recommended. However, smoking reduction can be considered where adolescents are not ready or able to stop smoking abruptly. As data are limited in this age group, and the recommended duration of NRT is 12 weeks, adolescents should consult a healthcare professional before starting the "smoking reduction prior to stopping" regimen.

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When making a quit attempt the smoking cessation instructions for adolescents (12 to 18 years) given above can be followed.

4.3. Contraindications

Hypersensitivity to nicotine or any component of the chewing gum.

4.4. Special warnings and precautions for use

Any risks that may be associated with NRT are substantially outweighed by the well established dangers of continued smoking.

Underlying cardiovascular disease: In stable cardiovascular disease Nicorette Ice Mint 4 mg Gum presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction, severe dysrhythmia or CVA and who are considered to be haemodynamically unstable should be encouraged to stop smoking with non-pharmacological interventions. If this fails, Nicorette Ice Mint 4 mg Gum may be
considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision.

_Diabetes mellitus:_ Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when NRT is initiated as catecholamines released by nicotine can affect carbohydrate metabolism.

_GI disease:_ Swallowed nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastritis or peptic ulcers and oral NRT preparations should be used with caution in these conditions. Ulcerative stomatitis has been reported.

_Renal or hepatic impairment:_ Nicorette Ice Mint 4 mg Gum should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

_Danger in small children:_ Doses of nicotine tolerated by adult and adolescent smokers can produce severe toxicity in small children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children. Nicotine gum should be disposed of with care.

_Phaeochromocytoma and uncontrolled hyperthyroidism:_ As nicotine causes release of catecholamines, Nicorette Ice Mint 4 mg Gum should be used with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma.

_Transferred dependence:_ Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

_Stopping smoking:_ Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole.

_Excipients:_ Nicorette Ice Mint 4 mg Gum also contains butylated hydroxy toluene (E321); this may cause irritation to the mucous membranes.

_Denture warning:_ Smokers who wear dentures may experience difficulty in chewing Nicorette Ice Mint 4 mg Gum. The chewing gum may stick to, and may in rare cases damage dentures.

4.5. **Interactions with other medicinal products and other forms of interaction**

No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

4.6. **Pregnancy and lactation**

_Pregnancy:_

NRT is not contraindicated in pregnancy. The decision to use NRT should be made on a risk-benefit assessment as early on in the pregnancy as possible with the aim of discontinuing use as soon as possible.

Smoking during pregnancy is associated with risks such as intra-uterine growth retardation, premature birth or stillbirth. Stopping smoking is the single most effective intervention for improving the health of both pregnant smoker and her baby. The earlier abstinence is achieved the better.

Ideally smoking cessation during pregnancy should be achieved without NRT. However for women unable to quit on their own, NRT may be recommended to assist a quit attempt.
Nicotine passes to the fetus affecting breathing movements and has a dose-dependent effect on placental/fetal circulation. However the risk of using NRT to the fetus is lower than that expected with tobacco smoking, due to lower maximal plasma nicotine concentration and no additional exposure to polycyclic hydrocarbons and carbon monoxide.

Intermittent dosing products may be preferable as these usually provide a lower daily dose of nicotine than patches. However, patches may be preferred if the woman is suffering from nausea during pregnancy. If patches are used they should be removed before going to bed.

Lactation
NRT is not contraindicated in lactation. Nicotine from smoking and NRT is found in breast milk. However the amount of nicotine the infant is exposed to is relatively small and less hazardous than the second-hand smoke they would otherwise be exposed to.

Using intermittent dose NRT preparations, compared with patches, may minimize the amount of nicotine in the breast milk as the time between administrations of NRT and feeding can be more easily prolonged.

4.7. Effects on ability to drive and use machines
Not applicable.

4.8. Undesirable effects
Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include; irritability/aggression, dysphoria/depressed mood, anxiety, restlessness, poor concentration, increased appetite/weight gain, urges to smoke (cravings), night-time awakenings/sleep disturbance and decreased heart rate.

Increased frequency of aphthous ulcer may occur after abstinence from smoking. The causality is unclear.

Nicorette Ice Mint 4 mg Gum may cause adverse reactions similar to those associated with nicotine given by other means, including smoking, and these are mainly dose-dependent. At recommended doses Nicorette Ice Mint 4 mg Gum has not been found to cause any serious adverse effects. Most of the undesirable effects reported by the patients occur during the first 3-4 weeks after start of treatment.

Excessive consumption of Nicorette Ice Mint 4 mg Gum by those who have not been in the habit of inhaling tobacco smoke could possibly lead to nausea, faintness or headaches. Excessive swallowing of dissolved nicotine may, at first, cause hiccupping.

Nicotine from the gum may sometimes cause a slight irritation of the throat at the start of treatment and may also cause increased salivation.

Those who are prone to indigestion may suffer initially from minor degrees of indigestion or heartburn if the 4mg nicotine gum is used; slower chewing and the use of the 2mg nicotine gum (if necessary more frequently) will usually overcome this problem.

The chewing gum may stick to, and may in rare cases damage dentures.

Reported adverse events associated with Nicorette 2mg and 4mg gum include:

<table>
<thead>
<tr>
<th>Body System</th>
<th>Incidence*</th>
<th>Reported adverse event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nervous system disorders:</td>
<td>Very common:</td>
<td>Headache</td>
</tr>
<tr>
<td></td>
<td>Common:</td>
<td>Dizziness</td>
</tr>
<tr>
<td>Cardiac disorders:</td>
<td>Uncommon:</td>
<td>Palpitations</td>
</tr>
<tr>
<td></td>
<td>Very rare:</td>
<td>Reversible atrial fibrillation</td>
</tr>
<tr>
<td>Gastrointestinal disorders:</td>
<td>Very common:</td>
<td>Gastrointestinal discomfort, hiccups, nausea</td>
</tr>
<tr>
<td></td>
<td>Common:</td>
<td>Vomiting</td>
</tr>
</tbody>
</table>
Body System | Incidence* | Reported adverse event
--- | --- | ---
Skin and subcutaneous tissue disorders: | Uncommon: | Erythema, urticaria
General disorders and administration site conditions: | Very common: | Sore mouth or throat, jaw-muscle ache
| Rare: | Allergic reactions including angioedema

* Very common (>1/10); common (>1/100, <1/10); uncommon (>1/1000, <1/100); rare (>1/10 000, <1/1 000); very rare (<1/10 000), including isolated reports.

4.9. **Overdose**

**Symptoms:** The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60mg. Symptoms of acute nicotine poisoning include nausea, salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. In extreme cases, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and terminal convulsions.

**Management of an overdose:** All nicotine intake should stop immediately and the patient should be treated symptomatically. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

5. **PHARMACOLOGICAL PROPERTIES**

5.1. **Pharmacodynamic properties**

Pharmacotherapeutic group: Drugs used in nicotine dependence

ATC code: N07B A01

The pharmacological effects of nicotine are well documented. Those resulting from chewing Nicorette Ice Mint 4 mg Gum are comparatively small. The response at any one time represents a summation of stimulant and depressant actions from direct, reflex and chemical mediator influences on several organs. The main pharmacological actions are central stimulation and/or depression; transient hyperpnoea; peripheral vasoconstriction (usually associated with a rise in systolic pressure); suppression of appetite and stimulation of peristalsis.

5.2. **Pharmacokinetic properties**

Nicotine administered in chewing gums is readily absorbed from the buccal mucous membranes. Demonstrable blood levels are obtained within 5 – 7 minutes and reach a maximum about 30 minutes after the start of chewing. Blood levels are roughly proportional to the amount of nicotine chewed and have been shown never to exceed those obtained from smoking cigarettes.

5.3. **Preclinical safety data**

Preclinical data indicate that nicotine is neither mutagenic nor genotoxic. There are no other findings derived from preclinical testing of relevance to the prescriber in determining the safety of the product which have not been considered in other relevant sections of this Summary of Product Characteristics.

6. **PHARMACEUTICAL PARTICULARS**

6.1. **List of excipients**

**Core Gum**
- Polacrilin
- Chewing gum base, containing butylated hydroxy toluene (E321)
- Xylitol
- Peppermint oil
- Sodium carbonate, anhydrous
- Acesulfame Potassium
- Levomenthol
- Magnesium oxide, light
- Quinoline yellow Al -lake (E104)
Talc

Coating
Xylitol
Peppermint oil
Acacia
Titanium dioxide (E171)
Quinoline yellow Al-lake (E104)
Carnauba wax

6.2. **Incompatibilities**
Not applicable.

6.3. **Shelf life**
2 Years.

6.4. **Special precautions for storage**
Do not store above 25°C.

6.5. **Nature and contents of container**
Blister packed strips each containing 15 pieces supplied in packs of 15, 30, 105 and 210 pieces.
Blister packed strips each containing 6 pieces supplied in packs of 12 pieces.
Not all pack sizes may be marketed.

6.6. **Instruction for use and handling (, and disposal)**
See section 4.2

7. **MARKETING AUTHORISATION HOLDER**
Pfizer Consumer Healthcare
Walton Oaks
Dorking Road
Walton-on-the -Hill
Surrey
KT20 7NS

8. **MARKETING AUTHORISATION NUMBER**
PL 15513/0144

9. **DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**
18/07/2006

10. **DATE OF REVISION OF THE TEXT**
18/07/2006
1. **NAME OF THE MEDICINAL PRODUCT**
Nicorette Spearmint 2mg Gum.

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION**
Chewing Gum containing 2mg nicotine, as nicotine resinate.

For excipients, see 6.1.

3. **PHARMACEUTICAL FORM**
Medicated Chewing Gum

A square, coated, white coloured piece of gum

4. **CLINICAL PARTICULARS**

4.1. **Therapeutic indications**
Nicorette Spearmint 2mg Gum is for the relief of nicotine withdrawal symptoms as an aid to smoking cessation in adults and children over 12 years of age. It is also indicated in pregnant and lactating women (see section 4.6).

In smokers currently unable or not ready to stop smoking abruptly, the gum may also be used as part of a programme to reduce smoking prior to stopping completely.

If possible, Nicorette Spearmint 2mg Gum should be used in conjunction with a behavioural support programme.

4.2. **Posology and method of administration**
Nicorette Spearmint 2mg Gum should be chewed slowly according to the instructions.

The strength of gum to be used will depend on the smoking habits of the individual. In general, if the patient smokes 20 or less cigarettes a day, 2mg nicotine gum is indicated. If more than 20 cigarettes per day are smoked, 4mg nicotine gum will be needed to meet the withdrawal of the high serum nicotine levels from heavy smoking.

The chewing gums should be used whenever there is an urge to smoke according to the “chew and rest” technique described on the pack. After about 30 minutes of such use, the gum will be exhausted. Not more than 15 pieces of the chewing gum may be used each day. Absorption of nicotine is through the buccal mucosa, any nicotine which is swallowed being destroyed by the liver.

Behavioural therapy, advice and support will normally improve the success rate.

**Smoking cessation**

*Adults (over 18 years of age)*

The patient should make every effort to stop smoking completely during treatment with Nicorette Spearmint 2mg Gum.

Use the gum whenever there is an urge to smoke to maintain complete abstinence from smoking. Sufficient gums should be used, usually 8-12, up to a maximum of 15.

Continue use for up to three months to break the habit of smoking, then gradually reduce gum use. When daily use is 1-2 gums, use should be stopped.

For those using 4 mg nicotine gum, the 2 mg nicotine gum will be helpful during withdrawal from treatment.

Any spare gum should be retained, as craving may suddenly return. Adults who use NRT beyond 9 months for smoking cessation are recommended to seek additional help and advice from a healthcare professional.
Adolescents (12 to 18 years)
The patient should make every effort to stop smoking completely during treatment with Nicorette Spearmint 2mg Gum.

Use the gum whenever there is an urge to smoke to maintain complete abstinence from smoking. Sufficient gums should be used, usually 8-12, up to a maximum of 15.

Continue use for up to 8 weeks to break the habit of smoking, then gradually reduce gum use over a 4 week period. When daily use is 1-2 gums, use should be stopped.

For those using 4 mg nicotine gum, the 2 mg nicotine gum will be helpful during withdrawal from treatment.

As data are limited in this age group, the recommended duration of treatment is 12 weeks. If longer treatment is required, advice from a healthcare professional should be sought.

Smoking reduction

Adults (over 18 years of age)
Use the gum between smoking episodes to manage the urge to smoke, to prolong smoke-free intervals and with the intention to reduce smoking as much as possible. If a reduction in number of cigarettes per day has not been achieved after 6 weeks, professional advice should be sought.

A quit attempt should be made as soon as the smoker feels ready, but not later than 6 months after start of treatment. If a quit attempt cannot be made within 9 months after starting treatment, professional advice should be sought.

When making a quit attempt the smoking cessation instructions above can be followed.

Adolescents (12 to 18 years)
Where adolescents are motivated to stop smoking abruptly, smoking cessation should be recommended. However, smoking reduction can be considered where adolescents are not ready or able to stop smoking abruptly. As data are limited in this age group, and the recommended duration of NRT is 12 weeks, adolescents should consult a healthcare professional before starting the "smoking reduction prior to stopping” regimen.

Use the gum between smoking episodes to manage the urge to smoke, to prolong smoke-free intervals and with the intention to reduce smoking as much as possible. If a reduction in number of cigarettes per day has not been achieved after 6 weeks, professional advice should be sought.

A quit attempt should be made as soon as the smoker feels ready, but not later than 6 months after start of treatment. If a quit attempt cannot be made within 9 months after starting treatment, professional advice should be sought.

When making a quit attempt the smoking cessation instructions for adolescents (12 to 18 years) given above can be followed.

4.3. Contraindications

Hypersensitivity to nicotine or any component of the chewing gum.

4.4. Special warnings and precautions for use

Any risks that may be associated with NRT are substantially outweighed by the well established dangers of continued smoking.

Underlying cardiovascular disease: In stable cardiovascular disease Nicorette Spearmint 2mg Gum presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction, severe dysrhythmia or CVA and who are considered to be haemodynamically unstable should be encouraged to stop smoking with non-pharmacological interventions. If this fails, Nicorette Spearmint 2mg Gum may be
considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision.

*Diabetes mellitus:* Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when NRT is initiated as catecholamines released by nicotine can affect carbohydrate metabolism.

*GI disease:* Swallowed nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastritis or peptic ulcers and oral NRT preparations should be used with caution in these conditions. Ulcerative stomatitis has been reported.

*Renal or hepatic impairment:* Nicorette Spearmint 2mg Gum should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

*Danger in small children:* Doses of nicotine tolerated by adult and adolescent smokers can produce severe toxicity in small children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children. Nicotine gum should be disposed of with care.

*Phaeochromocytoma and uncontrolled hyperthyroidism:* As nicotine causes release of catecholamines, Nicorette Spearmint 2mg Gum should be used with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma.

*Transferred dependence:* Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

*Stopping smoking:* Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole.

*Excipients:* Nicorette Spearmint 2mg Gum also contains butylated hydroxy toluene (E321); this may cause irritation to the mucous membranes.

*Denture warning:* Smokers who wear dentures may experience difficulty in chewing Nicorette Spearmint 2mg Gum. The chewing gum may stick to, and may in rare cases damage dentures.

4.5. **Interactions with other medicinal products and other forms of interaction**

No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

4.6. **Pregnancy and lactation**

**Pregnancy**

NRT is not contraindicated in pregnancy. The decision to use NRT should be made on a risk-benefit assessment as early on in the pregnancy as possible with the aim of discontinuing use as soon as possible.

Smoking during pregnancy is associated with risks such as intra-uterine growth retardation, premature birth or stillbirth. Stopping smoking is the single most effective intervention for improving the health of both pregnant smoker and her baby. The earlier abstinence is achieved the better.

Ideally smoking cessation during pregnancy should be achieved without NRT. However for women unable to quit on their own, NRT may be recommended to assist a quit attempt.
Nicotine passes to the fetus affecting breathing movements and has a dose-dependent effect on placental/fetal circulation. However the risk of using NRT to the fetus is lower than that expected with tobacco smoking, due to lower maximal plasma nicotine concentration and no additional exposure to polycyclic hydrocarbons and carbon monoxide.

Intermittent dosing products may be preferable as these usually provide a lower daily dose of nicotine than patches. However, patches may be preferred if the woman is suffering from nausea during pregnancy. If patches are used they should be removed before going to bed.

Lactation
NRT is not contraindicated in lactation. Nicotine from smoking and NRT is found in breast milk. However the amount of nicotine the infant is exposed to is relatively small and less hazardous than the second-hand smoke they would otherwise be exposed to.

Using intermittent dose NRT preparations, compared with patches, may minimize the amount of nicotine in the breast milk as the time between administrations of NRT and feeding can be more easily prolonged.

4.7. Effects on ability to drive and use machines
Not applicable.

4.8. Undesirable effects
Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include; irritability/aggression, dysphoria/depressed mood, anxiety, restlessness, poor concentration, increased appetite/weight gain, urges to smoke (cravings), night-time awakenings/sleep disturbance and decreased heart rate.

Increased frequency of aphthous ulcer may occur after abstinence from smoking. The causality is unclear.

Nicorette Spearmint 2mg Gum may cause adverse reactions similar to those associated with nicotine given by other means, including smoking, and these are mainly dose-dependent. At recommended doses Nicorette Spearmint 2mg Gum has not been found to cause any serious adverse effects. Most of the undesirable effects reported by the patients occur during the first 3-4 weeks after start of treatment.

Excessive consumption of Nicorette Spearmint 2mg Gum by those who have not been in the habit of inhaling tobacco smoke could possibly lead to nausea, faintness or headaches. Excessive swallowing of dissolved nicotine may, at first, cause hiccupping.

Nicotine from the gum may sometimes cause a slight irritation of the throat at the start of treatment and may also cause increased salivation.

Those who are prone to indigestion may suffer initially from minor degrees of indigestion or heartburn if the 4mg nicotine gum is used; slower chewing and the use of the 2mg nicotine gum (if necessary more frequently) will usually overcome this problem.

The chewing gum may stick to, and may in rare cases damage dentures.

Reported adverse events associated with Nicorette 2mg and 4mg gum include:

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<th>Incidence*</th>
<th>Reported adverse event</th>
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<td>Cardiac disorders:</td>
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<td>Gastrointestinal discomfort, hiccups, nausea</td>
</tr>
<tr>
<td></td>
<td>Common:</td>
<td>Vomiting</td>
</tr>
</tbody>
</table>
**Body System**

**Incidence**

**Reported adverse event**

<table>
<thead>
<tr>
<th>Disorder</th>
<th>Incidence</th>
<th>Reported adverse event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin and subcutaneous tissue disorders:</td>
<td>Uncommon</td>
<td>Erythema, urticaria</td>
</tr>
<tr>
<td>General disorders and administration site conditions:</td>
<td>Very common</td>
<td>Sore mouth or throat, jaw-muscle ache</td>
</tr>
<tr>
<td></td>
<td>Rare</td>
<td>Allergic reactions including angioedema</td>
</tr>
</tbody>
</table>

* Very common (>1/10); common (>1/100, <1/10); uncommon (>1/1 000, <1/100); rare (>1/10 000, <1/1 000); very rare (<1/10 000), including isolated reports.

### 4.9. Overdose

**Symptoms:** The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60mg. Symptoms of acute nicotine poisoning include nausea, salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. In extreme cases, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and terminal convulsions.

**Management of an overdose:** All nicotine intake should stop immediately and the patient should be treated symptomatically. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

### 5. PHARMACOLOGICAL PROPERTIES

#### 5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Drugs used in nicotine dependence

ATC code: N07B A01

The pharmacological effects of nicotine are well documented. Those resulting from chewing Nicorette Spearmint 2mg Gum are comparatively small. The response at any one time represents a summation of stimulant and depressant actions from direct, reflex and chemical mediator influences on several organs. The main pharmacological actions are central stimulation and/or depression; transient hyperpnoea; peripheral vasoconstriction (usually associated with a rise in systolic pressure); suppression of appetite and stimulation of peristalsis.

#### 5.2. Pharmacokinetic properties

Nicotine administered in chewing gums is readily absorbed from the buccal mucous membranes. Demonstrable blood levels are obtained within 5 – 7 minutes and reach a maximum about 30 minutes after the start of chewing. Blood levels are roughly proportional to the amount of nicotine chewed and have been shown never to exceed those obtained from smoking cigarettes.

#### 5.3. Preclinical safety data

Preclinical data indicate that nicotine is neither mutagenic nor genotoxic. There are no other findings derived from preclinical testing of relevance to the prescriber in determining the safety of the product which have not been considered in other relevant sections of this Summary of Product Characteristics.

### 6. PHARMACEUTICAL PARTICULARS

#### 6.1. List of excipients

**Core Gum**

- Polacrilin
- Chewing gum base, containing butylated hydroxy toluene (E321)
- Xylitol
- Peppermint oil
- Sodium carbonate, anhydrous
- Sodium hydrogen carbonate
- Acesulfame Potassium
- Levomenthol
- Magnesium oxide, light
- Talc
UKPAR Nicorette Ice Mint and Spearmint 2 and 4 mg Gum (PL 15513/0143-4 & 152-3)

Coating
Xylitol
Peppermint oil
Acacia
Titanium dioxide (E171)
Carnauba wax

6.2. **Incompatibilities**
Not applicable.

6.3. **Shelf life**
2 Years

6.4. **Special precautions for storage**
Do not store above 25°C.

6.5. **Nature and contents of container**
PVC/PVDC/Al Blister packed strips each containing 15 pieces supplied in packs of 15, 30, 105 and 210 pieces.
Blister packed strips each containing 6 pieces supplied in packs of 12 pieces.
Not all pack sizes may be marketed.

6.6. **Instruction for use and handling (, and disposal)**
See section 4.2

7. **MARKETING AUTHORISATION HOLDER**
Pfizer Consumer Healthcare
Walton Oaks
Dorking Road
Walton-on-the-Hill
Surrey
KT20 7NS

8. **MARKETING AUTHORISATION NUMBER**
PL 15513/0152

9. **DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**
18/07/2006

10. **DATE OF REVISION OF THE TEXT**
18/07/2006
1. **NAME OF THE MEDICINAL PRODUCT**
Nicorette Spearmint 4mg Gum

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION**
Chewing Gum containing 4mg nicotine, as nicotine resinate.

For excipients, see 6.1.

3. **PHARMACEUTICAL FORM**
Medicated Chewing Gum

A square, coated, crème coloured piece of gum

4. **CLINICAL PARTICULARS**

4.1. **Therapeutic indications**
Nicorette Spearmint 4mg Gum is for the relief of nicotine withdrawal symptoms as an aid to smoking cessation in adults and children over 12 years of age. It is also indicated in pregnant and lactating women (see section 4.6).

In smokers currently unable or not ready to stop smoking abruptly, the gum may also be used as part of a programme to reduce smoking prior to stopping completely.

If possible, Nicorette Spearmint 4mg Gum should be used in conjunction with a behavioural support programme.

4.2. **Posology and method of administration**
Nicorette Spearmint 4 mg Gum should be chewed slowly according to the instructions.

The strength of gum to be used will depend on the smoking habits of the individual. In general, if the patient smokes 20 or less cigarettes a day, 2mg nicotine gum is indicated. If more that 20 cigarettes per day are smoked, 4mg nicotine gum will be needed to meet the withdrawal of the high serum nicotine levels from heavy smoking.

The chewing gums should be used whenever there is an urge to smoke according to the “chew and rest” technique described on the pack. After about 30 minutes of such use, the gum will be exhausted. Not more than 15 pieces of the chewing gum may be used each day.

Absorption of nicotine is through the buccal mucosa, any nicotine which is swallowed being destroyed by the liver.

Behavioural therapy, advice and support will normally improve the success rate.

**Smoking cessation**

*Adults (over 18 years of age)*

The patient should make every effort to stop smoking completely during treatment with Nicorette Spearmint 4 mg Gum.

Use the gum whenever there is an urge to smoke to maintain complete abstinence from smoking. Sufficient gums should be used, usually 8-12, up to a maximum of 15.

Continue use for up to three months to break the habit of smoking, then gradually reduce gum use. When daily use is 1-2 gums, use should be stopped.

For those using 4 mg nicotine gum, the 2 mg nicotine gum will be helpful during withdrawal from treatment.

Any spare gum should be retained, as craving may suddenly return. Adults who use NRT beyond 9 months for smoking cessation are recommended to seek additional help and advice from a healthcare professional.
Adolescents (12 to 18 years)
The patient should make every effort to stop smoking completely during treatment with Nicorette Spearmint 4 mg Gum.

Use the gum whenever there is an urge to smoke to maintain complete abstinence from smoking. Sufficient gums should be used, usually 8-12, up to a maximum of 15.

Continue use for up to 8 weeks to break the habit of smoking, and then gradually reduce gum use over a 4 week period. When daily use is 1-2 gums, use should be stopped. For those using 4 mg nicotine gum, the 2 mg nicotine gum will be helpful during withdrawal from treatment.

As data are limited in this age group, the recommended duration of treatment is 12 weeks. If longer treatment is required, advice from a healthcare professional should be sought.

Smoking reduction
Adults (over 18 years of age)
Use the gum between smoking episodes to manage the urge to smoke, to prolong smoke-free intervals and with the intention to reduce smoking as much as possible. If a reduction in number of cigarettes per day has not been achieved after 6 weeks, professional advice should be sought.

A quit attempt should be made as soon as the smoker feels ready, but not later than 6 months after start of treatment. If a quit attempt cannot be made within 9 months after starting treatment, professional advice should be sought.

When making a quit attempt the smoking cessation instructions above can be followed.

Adolescents (12 to 18 years)
Where adolescents are motivated to stop smoking abruptly, smoking cessation should be recommended. However, smoking reduction can be considered where adolescents are not ready or able to stop smoking abruptly. As data are limited in this age group, and the recommended duration of NRT is 12 weeks, adolescents should consult a healthcare professional before starting the “smoking reduction prior to stopping” regimen.

Use the gum between smoking episodes to manage the urge to smoke, to prolong smoke-free intervals and with the intention to reduce smoking as much as possible. If a reduction in number of cigarettes per day has not been achieved after 6 weeks, professional advice should be sought.

A quit attempt should be made as soon as the smoker feels ready, but not later than 6 months after start of treatment. If a quit attempt cannot be made within 9 months after starting treatment, professional advice should be sought.

When making a quit attempt the smoking cessation instructions for adolescents (12 to 18 years) given, above can be followed.

4.3. Contraindications
Hypersensitivity to nicotine or any component of the chewing gum.

4.4. Special warnings and precautions for use
Any risks that may be associated with NRT are substantially outweighed by the well established dangers of continued smoking.

Underlying cardiovascular disease: In stable cardiovascular disease Nicorette Spearmint 4 mg Gum presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction, severe dysrhythmia or CVA and who are considered to be haemodynamically unstable should be encouraged to stop smoking with non-pharmacological interventions.
If this fails, Nicorette Spearmint 4 mg Gum may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision.

*Diabetes mellitus:* Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when NRT is initiated as catecholamines released by nicotine can affect carbohydrate metabolism.

*GI disease:* Swallowed nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastritis or peptic ulcers and oral NRT preparations should be used with caution in these conditions. Ulcerative stomatitis has been reported.

*Renal or hepatic impairment:* Nicorette Spearmint 4 mg Gum should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

*Danger in small children:* Doses of nicotine tolerated by adult and adolescent smokers can produce severe toxicity in small children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children. Nicotine gum should be disposed of with care.

*Phaeochromocytoma and uncontrolled hyperthyroidism:* As nicotine causes release of catecholamines, Nicorette Spearmint 4 mg Gum should be used with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma.

*Transferred dependence:* Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

*Stopping smoking:* Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole.

*Excipients:* Nicorette Spearmint 4 mg Gum also contains butylated hydroxy toluene (E321); this may cause irritation to the mucous membranes.

*Denture warning:* Smokers who wear dentures may experience difficulty in chewing Nicorette Spearmint 4 mg Gum. The chewing gum may stick to, and may in rare cases damage dentures.

### 4.5. Interactions with other medicinal products and other forms of interaction

No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

### 4.6. Pregnancy and lactation

**Pregnancy**

NRT is not contraindicated in pregnancy. The decision to use NRT should be made on a risk-benefit assessment as early on in the pregnancy as possible with the aim of discontinuing use as soon as possible.

Smoking during pregnancy is associated with risks such as intra-uterine growth retardation, premature birth or stillbirth. Stopping smoking is the single most effective intervention for improving the health of both pregnant smoker and her baby. The earlier abstinence is achieved the better.

Ideally smoking cessation during pregnancy should be achieved without NRT. However for women unable to quit on their own, NRT may be recommended to assist a quit attempt.
Nicotine passes to the fetus affecting breathing movements and has a dose-dependent effect on placental/fetal circulation. However the risk of using NRT to the fetus is lower than that expected with tobacco smoking, due to lower maximal plasma nicotine concentration and no additional exposure to polycyclic hydrocarbons and carbon monoxide.

Intermittent dosing products may be preferable as these usually provide a lower daily dose of nicotine than patches. However, patches may be preferred if the woman is suffering from nausea during pregnancy. If patches are used they should be removed before going to bed.

Lactation
NRT is not contraindicated in lactation. Nicotine from smoking and NRT is found in breast milk. However the amount of nicotine the infant is exposed to is relatively small and less hazardous than the second-hand smoke they would otherwise be exposed to.

Using intermittent dose NRT preparations, compared with patches, may minimize the amount of nicotine in the breast milk as the time between administrations of NRT and feeding can be more easily prolonged.

4.7. Effects on ability to drive and use machines
Not applicable.

4.8. Undesirable effects
Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include; irritability/aggression, dysphoria/depressed mood, anxiety, restlessness, poor concentration, increased appetite/weight gain, urges to smoke (cravings), night-time wakeings/sleep disturbance and decreased heart rate.

Increased frequency of aphthous ulcer may occur after abstinence from smoking. The causality is unclear.

Nicorette Spearmint 4 mg Gum may cause adverse reactions similar to those associated with nicotine given by other means, including smoking, and these are mainly dose-dependent. At recommended doses Nicorette Spearmint 4 mg Gum has not been found to cause any serious adverse effects. Most of the undesirable effects reported by the patients occur during the first 3-4 weeks after start of treatment.

Excessive consumption of Nicorette Spearmint 4 mg Gum by those who have not been in the habit of inhaling tobacco smoke could possibly lead to nausea, faintness or headaches. Excessive swallowing of dissolved nicotine may, at first, cause hiccupping.

Nicotine from the gum may sometimes cause a slight irritation of the throat at the start of treatment and may also cause increased salivation.

Those who are prone to indigestion may suffer initially from minor degrees of indigestion or heartburn if the 4mg nicotine gum is used; slower chewing and the use of the 2mg nicotine gum (if necessary more frequently) will usually overcome this problem.

The chewing gum may stick to, and may in rare cases damage dentures.

Reported adverse events associated with Nicorette 2mg and 4mg gum include:

<table>
<thead>
<tr>
<th>Body System</th>
<th>Incidence*</th>
<th>Reported adverse event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nervous system disorders:</td>
<td>Very common:</td>
<td>Headache</td>
</tr>
<tr>
<td>Cardiac disorders:</td>
<td>Common:</td>
<td>Dizziness</td>
</tr>
<tr>
<td>Gastrointestinal disorders:</td>
<td>Uncommon:</td>
<td>Palpitations</td>
</tr>
<tr>
<td></td>
<td>Very rare:</td>
<td>Reversible atrial fibrillation</td>
</tr>
<tr>
<td></td>
<td>Very common:</td>
<td>Gastrointestinal discomfort, hiccups, nausea</td>
</tr>
<tr>
<td></td>
<td>Common:</td>
<td>Vomiting</td>
</tr>
</tbody>
</table>
4.9. Overdose

Symptoms: The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60mg. Symptoms of acute nicotine poisoning include nausea, salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. In extreme cases, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and terminal convulsions.

Management of an overdose: All nicotine intake should stop immediately and the patient should be treated symptomatically. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

5. PHARMACOLOGICAL PROPERTIES

5.2. Pharmacodynamic properties

Pharmacotherapeutic group: Drugs used in nicotine dependence
ATC code: N07B A01

The pharmacological effects of nicotine are well documented. Those resulting from chewing Nicorette Spearmint 4 mg Gum are comparatively small. The response at any one time represents a summation of stimulant and depressant actions from direct, reflex and chemical mediator influences on several organs. The main pharmacological actions are central stimulation and/or depression; transient hyperpnoea; peripheral vasoconstriction (usually associated with a rise in systolic pressure); suppression of appetite and stimulation of peristalsis.

5.2. Pharmacokinetic properties

Nicotine administered in chewing gums is readily absorbed from the buccal mucous membranes. Demonstrable blood levels are obtained within 5 – 7 minutes and reach a maximum about 30 minutes after the start of chewing. Blood levels are roughly proportional to the amount of nicotine chewed and have been shown never to exceed those obtained from smoking cigarettes.

5.3. Preclinical safety data

Preclinical data indicate that nicotine is neither mutagenic nor genotoxic. There are no other findings derived from preclinical testing of relevance to the prescriber in determining the safety of the product which have not been considered in other relevant sections of this Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Core Gum
Polacrilin
Chewing gum base, containing butylated hydroxy toluene (E321)
Xylitol
Peppermint oil
Sodium carbonate, anhydrous
Acesulfame Potassium
Levomenthol
Magnesium oxide, light
Quinoline yellow Al-lake (E104)
Talc
Coating
Xylitol
Peppermint oil
Acacia
Titanium dioxide (E171)
Quinoline yellow Al-lake (E104)
Carnauba wax

6.2. Incompatibilities
Not applicable.

6.3. Shelf life
2 Years

6.4. Special precautions for storage
Do not store above 25°C.

6.5. Nature and contents of container
Blister packed strips each containing 15 pieces supplied in packs of 15, 30, 105 and 210 pieces.
Blister packed strips each containing 6 pieces supplied in packs of 12 pieces.
Not all pack sizes may be marketed.

6.6. Instruction for use and handling (use and disposal)
See section 4.2

7. MARKETING AUTHORISATION HOLDER
Pfizer Consumer Healthcare
Walton Oaks
Dorking Road
Walton-on-the -Hill
Surrey
KT20 7NS

8. MARKETING AUTHORISATION NUMBER
PL 15513/0153

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
18/07/2006

10. DATE OF REVISION OF THE TEXT
18/07/2006
2 mg strength:

A Guide for Users

What should you know about
nicorette® Peppermint 2mg Gum
(2mg nicotine chewing gum)
Low strength
nicorette® Ice Mint 2mg Gum
(2mg nicotine chewing gum)
Low strength
nicorette® Spearmint 2mg Gum
(2mg nicotine chewing gum)
Low strength

Please read this leaflet carefully before
you start using this medicine. It provides
useful information on how to use it
safely. The information applies only to
this product. If you have any questions,
or you are not sure about anything
please ask your doctor or pharmacist.

REMEMBER: This medicine is for you.
Never give it to others. It may harm
them even if their symptoms are the
same as yours.

What is Nicorette Gum?

Nicorette Peppermint, Ice Mint and
Spearmint 2mg Gum:
Each gum contains 2 milligrams of
nicotine, which is the active ingredient.

Other ingredients are:
Chewing gum base, xylitol, aceulfraine
potassium, sodium carbonate, peppermint
oil, levomenthol, pectin, magnesium
oxide, sodium hydrogen carbonate,
titanium dioxide E171 (white colour), talc,
acacia and carnauba wax.
The chewing gum base contains butylated hydroxytoluene, (E321), an anti-oxidant. None of the gums contain sugar (sucrose) or animal products.

The gums are blister packed in sheets of 6 or 15 and supplied in packs of 12, 15, 30, 105 or 210 pieces. Not all pack sizes may be marketed.

Who makes Nicorette Gum?

Your medicine is made by Pfizer Health AB, Helsingborg, Sweden.

The Marketing Authorisation is held by Pfizer Consumer Healthcare, Walton-on-the-Hill, Surrey, KT20 7NS.

What is Nicorette Gum used for?

Nicorette Gum is a nicotine replacement therapy (NRT). It is used to relieve withdrawal symptoms and reduce the cravings for nicotine which people get when they stop smoking or when they are cutting down the number of cigarettes they smoke while trying to stop smoking.

If you smoke 20 or fewer cigarettes a day, this product will help relieve your cravings.

If you smoke more than 20 cigarettes a day, 4mg nicotine gum may be more appropriate.

What does Nicorette Gum do?

When you stop smoking or cut down the number of cigarettes you smoke, your body misses the nicotine that you have been absorbing from the tobacco smoke. You may experience unpleasant feelings and a strong desire to smoke (‘craving’). This shows that you were dependent on nicotine. However, the toxins in cigarette smoke such as tar, lead, cyanide and ammonia cause smoking related disease and death, rather than nicotine. The benefits of stopping smoking far outweigh any potential risk from using nicotine from NRT.

When you chew Nicorette Gum nicotine is released and passes into your body through the lining of your mouth. The nicotine released from the gum is sufficient to relieve the unpleasant withdrawal symptoms. It will also help to stop the craving to smoke but Nicorette Gum will not give you the ‘buzz’ you get from a cigarette. Make sure you chew Nicorette Gum correctly to get the best effect – see ‘How to chew Nicorette Gum – the Nicorette Chewing Technique’.

As well as the effects of nicotine, you could be very attached to the habit of smoking. For example, lighting up after a meal or in certain situations or when you are with particular people. These rituals are part of your smoking habit which you may have had for many years. To succeed in giving up you should try to avoid situations where you may be tempted to smoke. Think about the times when you are most likely to miss smoking and try to plan how you will cope on these occasions. Changing your routine will help you to break the habit of smoking.

Encouragement and support from your doctor, nurse, pharmacist, friends and family can make giving up less stressful and more successful. For professional advice about giving up smoking, ask your doctor, nurse or pharmacist.
UKPAR Nicorette Ice Mint and Spearmint 2 and 4 mg Gum (PL 15513/0143-4 & 152-3)

Do not use Nicorette Gum if:

* you have an allergy to nicotine or any of the other ingredients in your Nicorette Gum.

Before you use Nicorette Gum:

There are some circumstances (listed below) where you should consult your doctor, nurse or pharmacist before using Nicorette Gum:

* If you are pregnant or breast-feeding – as you should try and give up smoking without the use of nicotine replacement therapy. (See "What if you are pregnant or breast-feeding?"
* If you have heart disease (including heart attack and disorders of heart rate and/or rhythm) or stroke for which you are in hospital. In other heart conditions not requiring you to be in hospital, using NRT is better than continuing to smoke.
* If you have high blood pressure that is not adequately controlled by treatment.
* If you have a stomach or duodenal ulcer and/or inflammation of the oesophagus (passage between the mouth and stomach).
* If you have serious liver or kidney disease.

What if you are pregnant or breast-feeding?

Pregnancy

Smoking during pregnancy is associated with risks such as poor growth of the baby before birth, premature birth or stillbirth. Stopping smoking is the single most effective intervention for improving both your health and that of your baby and the earlier smoking stops the better.

Ideally, stopping smoking during pregnancy should be achieved without NRT. However if you have tried and this is not possible, NRT may be recommended to help as the risk to the developing baby is less than that expected from continued smoking. The decision to use NRT should be made as early on in the pregnancy as possible with the aim of discontinuing use as soon as possible.

Products that are taken intermittently may be preferable to nicotine patches. However, patches may be preferred if you have nausea or sickness. Patches, if used, should be removed before going to bed at night.

Breast-feeding

Tobacco smoke produces breathing and other problems in babies and children. If you need to use NRT to help you quit, the amount of nicotine that the baby may receive is considerably smaller and less harmful than the second-hand smoke they would otherwise be breathing in. You are best to use NRT products that are taken intermittently (i.e. not patches) and try to breast-feed at a time just before you take the product to ensure that the baby gets the smallest amount of nicotine possible.

When to use Nicorette Gum and for how long?

Adults over 18 years of age

Because smoking is an addiction you may find it difficult to give up. Some people may find it easier to set a quit date and stop smoking immediately. Others may benefit from gradually reducing the number of cigarettes they smoke each day until they feel able to set a quit date. If you are ready to stop smoking immediately, follow Programme 1. If you are not ready to quit immediately but would rather stop smoking gradually, follow Programme 2.
**Dosage Instructions**

**How many pieces should you take:**
Most people use around 18 pieces of gum a day. You should not use more than 15 pieces a day. Use only one piece of gum at a time.

**How to chew the gum:**
Chew it as explained in the section 'How to chew Nicorette Gum - the Nicorette Chewing Technique'.

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**Programme 1 (Stopping Immediately)**

**Step 1:** 0 – 3 months
Set yourself a quit date, when you are not too stressed and ready to stop smoking. Over a period of 3 months use the gum to replace the cravings to smoke.

**Step 2:** Weaning period
After 3 months should be able to reduce the use of the gum. You should try to use fewer pieces of gum each day. When you are using only one or two pieces per day, you should stop completely. However, you should remember that you might feel a sudden craving to smoke long after you've given up and you can use the gum again if this should happen.

If you need to use the product for longer than 9 months, ask your doctor, nurse or pharmacist for advice.

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**Programme 2 (Stopping Gradually)**

**Step 1:** 0 – 6 weeks
Establish how many cigarettes you smoke. Set yourself a date when you decide to reduce the number of cigarettes you smoke. Use Nicorette Gum when you feel the urge to smoke and with the intention to reduce your smoking as much as possible. If after 6 weeks you have not managed to reduce the number of cigarettes you smoke, consult your doctor.

**Step 2:** 6 weeks – 6 months
If you have managed to reduce the number of cigarettes you smoke after 6 weeks, continue to use Nicorette Gum to reduce your smoking progressively until you feel ready to attempt to stop smoking completely. You should aim to stop smoking completely by 6 months. If you have not made a serious attempt to stop smoking completely within 6 months, you should speak to your doctor.

**Step 3:** 6 months – 9 months
When you're ready to stop smoking completely, cut out all cigarettes and continue to use Nicorette Gum for up to another 3 months to replace the cravings to smoke.

**Step 4:** Weaning period
3 months after having stopped smoking completely, you should be able to reduce the use of the gum. You should try to use fewer pieces of gum each day. When you are using only one or two pieces per day, you should stop completely. However, you should remember that you might feel a sudden craving to smoke long after you've given up and you can use the gum again if this should happen. If you need to use the product for longer than 9 months from the time you give up cigarettes, ask your doctor, nurse or pharmacist for advice.

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**Children 12 years and over**

Use the number of pieces of gum as recommended for adults. Children 12 years and over should only use NRT for up to 12 weeks. The steps below should be followed when using this product.

**Stopping Immediately (Programme 1)**

**Step 1:** Over an 8 week period try the gum to replace the cravings to smoke.

**Step 2:** After 8 weeks reduce the use of the gum over the next 4 weeks. You should try to use fewer pieces of gum each day. When you reduce usage to only 1 or 2 pieces per day, you should stop completely.

If you need to use this medicine for longer than 12 weeks, consult your doctor, nurse or pharmacist for advice.

**Stopping gradually (Programme 2)**

**Step 1:** Over a period of 8 weeks try the gum to replace the cravings to smoke.

**Step 2:** After 8 weeks reduce the use of the gum over the next 4 weeks. You should try to use fewer pieces of gum each day. When you reduce usage to only 1 or 2 pieces per day, you should stop completely.

If you need to use this medicine for longer than 12 weeks, consult your doctor, nurse or pharmacist for advice before using attempting to stop gradually.

Do not give to children under 12 years.

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**How to chew Nicorette Gum - the Nicorette Chewing Technique**

The method of chewing Nicorette Gum is not the same as for ordinary chewing gum. Nicorette Gum is chewed to release nicotine then rinsed so that nicotine can be taken in through the lining of the mouth. If Nicorette Gum is chewed continuously, the nicotine is released too quickly and is swallowed. This may irritate your throat, upset your stomach or give you hiccup.

If you have false teeth you may have difficulty chewing the gum as Nicorette Gum could stick to them and on rare occasions, damage dentures. If you experience a problem, other types of nicotine replacement therapy such as a skin patch, inhalator or sublingual tablets may be more suitable for you.

The Nicorette Chewing Technique

1. Chew slowly until taste becomes strong
2. Rest between gum and cheek
3. Chew again when the taste has faded
   - Chew a piece of Nicorette Gum when you feel the urge to smoke.
• Only use one gum at a time and use the Nicorette Chewing Technique.
• Keep chewing like this for about half an hour.
• After this time the gum will have lost its strength and you should dispose of it carefully.
• Most people use around 10 pieces of gum a day. You should not use more than 15 pieces a day. Do not exceed the stated dose.

What should you do if you have taken too much Nicorette Gum?
If you have used more than the recommended number of pieces of Nicorette Gum you may experience nausea, salivation, pain in your abdomen, sweating, headache, dizziness, hearing disturbance, or weakness. If any unwanted effects occur contact a doctor or your nearest hospital. Accident and Emergency department immediately. If you go to the doctor or hospital, take this leaflet and the pack with you.

What should you do if a child has taken Nicorette Gum?
If a child chews or swallows Nicorette Gum contact a doctor or your nearest hospital.

Very rarely abnormal beating of the heart has been reported.
If you develop an allergic reaction (swelling of the mouth and tongue, itching of the skin, ulceration and inflammation of the lining of the mouth), palpitations, an uneven (irregular) heartbeat or bad indigestion, stop using the Nicorette Gum, do not smoke and contact a doctor immediately.
You may experience some unwanted effects because of stopping smoking you have reduced the amount of nicotine you are taking. These effects are nicotine withdrawal symptoms and include irritability/agitation, feeling low, anxiety, restlessness, poor concentration, increased appetite/weight gain, urge to smoke ('craving'), night-time awakening, sleep disturbance and lowering of your heart rate. You may experience nicotine withdrawal symptoms if you use too few pieces of Nicorette Gum before you are ready to reduce your nicotine intake.

When you stop smoking, you may experience mouth ulcers. The reason why this happens is unknown.
If you find it difficult to cut down and stop using Nicorette Gum, or are worried that without it you will start smoking again, talk to your doctor, nurse or pharmacist.
Remember; Nicorette Gum is not intended as a substitute for smoking, it is an aid to giving up.
If you notice these or any other unwanted effects not listed in this leaflet you should tell your doctor, nurse or pharmacist.

Are there any unwanted effects from Nicorette Gum?
Like all medicines, Nicorette Gum can have side-effects. These effects are rarely serious.
As many of the effects are due to nicotine they can also occur when nicotine is obtained by smoking.
Some unwanted effects you may notice when you start to use Nicorette Gum for the first time include: hiccup, sore throat, increased saliva in your mouth, mild indigestion or heartburn. These effects may be due to using too much Nicorette Gum, chewing it continuously, or swallowing too much nicotine released from the gum. You may also feel sick or faint or get headaches. Please read the chewing instructions again.
Other commonly reported side-effects include dizziness, vomiting, sore mouth or jaw-muscle ache. Chest palpitations, redness or itching of the skin have also occurred but reports of this are uncommon.

Taking care of your Nicorette Gum
Do not use the gum after the 'Use before' date on the box or blister strip.
Keep Nicorette Gum out of reach and sight of children and pets as nicotine in high doses can be very dangerous and sometimes fatal if taken by small children. Do not store Nicorette Gum above 25°C. Dispose of Nicorette Gum sensibly.
Helpful Tips on Giving Up

You may have tried to stop smoking before and you know from bitter experience that it's not easy to give up cigarettes. However, you have now taken the first constructive step towards becoming a non-smoker. In overcoming your tobacco dependence you will have to tackle two problems:

1. Your SMOKING HABIT
2. Your ADDICTION to nicotine

Willpower

The overriding success factor in quitting is how determined you are. The first few weeks of quitting or reducing the number of cigarettes you smoke will probably be the most difficult because your smoking ritual is still fresh in your mind. However, you will find that as time goes by, your willpower becomes stronger.

Telling friends, family and work colleagues that you have quit smoking and that you envisage a tough time ahead will encourage them to support you.

Pick the right day.
There is never a perfect time to give up smoking, but you should plan ahead by choosing a date in the not too distant future on which you are going to give up cigarettes completely or start reducing the number of cigarettes you smoke. This is your Quit Day. Try to pick a day when you will not be too stressed.

Break your routine.
For a number of years you will have become accustomed to smoking at certain times, with particular people or in certain situations. Think about the times you will miss smoking the most and plan how you will cope on these occasions. Changing your routine will help you break the habit of smoking. It may be helpful, if you are reducing the number of cigarettes you are smoking before stopping smoking, to think about how you will reduce the number of cigarettes you smoke and draw up a plan. You may choose to focus on the cigarettes you find least enjoyable and eliminate them first.

Quit with a friend.
Quitting with a fellow smoker is a good idea. It will strengthen your resolve and build on your determination. Encourage a friend or family member to quit with you. It will give your morale a boost since there will be another person knowing exactly what you're feeling and with whom you can share your resolve to quit smoking.

Remove any temptation.
When stopping smoking completely, to help yourself succeed, be sure to remove all cigarettes, matches, lighters etc. from your home, car and work. Ask your friends and colleagues not to offer you cigarettes or smoke close by you – but be careful not to offend them. Explain that you have given up. This type of support from friends is of greatest benefit for the first couple of weeks of quitting, as this is your most vulnerable time. The last thing you want is a cigarette close at hand in a moment of weakness.

Take one day at a time.
When you reach your Quit Day, don’t allow yourself to think that you’re quitting for good. That will make it seem like a superhuman task. Just promise yourself “I won’t have a cigarette today”, and take it one day at a time. You’ll be surprised how much that little thought helps.

Distract yourself.
Whenever you feel the urge to smoke coming on, distract yourself by keeping active. Don’t feel sorry for yourself. Get up and DO something. Do that job around the house or garden that you’ve been putting off, or take up a hobby. Remember that the craving only lasts a few minutes.
Learn to relax.
Once you have stopped smoking, taking
exercise regularly will not only help you
gain fitter but will encourage you to
relax. Exercise has the ability to relieve
stress and tension. Taken regularly it will
benefit you physically and psychologically. If you haven’t exercised for some
time, take it slowly to begin with and
increase the amount of time spent
exercising over the course of a few
weeks. Not only will exercising help you
relax but also helps to keep your weight
under control, which some people find a
problem when quitting.

Think cash not ash.
One of the really noticeable benefits of
"stopping" is the extra cash that’s
suddenly available. To emphasise the
point put the money into a pot marked
“cash not ash” and watch it accumulate.
But be sure to use the money to treat
yourself. You deserve a REWARD for
NOT smoking.

Dealing with relapses.
After you have stopped smoking you
might find that in times of stress, reaching
for a cigarette is the only thing that will
help you through. There may also be
certain situations – particularly social
situations such as a party or in the pub –
where temptation just gets the better of
you, so you smoke one or two
cigarettes. You might feel that your only
option is to go back to smoking. Don’t
think of it as having failed, just think
through the reasons why you wanted to
quit in the first place and don’t let those
couple of cigarettes get the better of you.
Refer back to your plan and start again.
You can beat it!

If you don’t succeed.
Giving up is more difficult for some
people than others. If you fail to stop
first time, don’t be disheartened. Try
again at a later date – you CAN do it!
Remember the most successful long
term ex-smokers have usually had to try
several times to stop smoking... if you
don’t succeed – quit quit again.

For further information:
Please read the attached leaflet "We’ll
Help You Make a Fresh Start" which
contains details of the Nicorette* Fresh
Start Complete Quitters Support
Programme.

Date of preparation of this leaflet:
December 2005 ©

Nicorette is a registered trademark
UKPAR Nicorette Ice Mint and Spearmint 2 and 4 mg Gum (PL 15513/0143-4 & 152-3)

fresh start
Complete Quitter's Support Programme

How can Fresh Start help me?

Together with your choice of Nicorette, the Fresh Start Programme can greatly increase your chance of success.

As a Fresh Start Committed Quitter we'll send you lots of useful information on stopping smoking plus encouragement and advice on how you can stay stopped.

Enrolling on the programme couldn't be easier. Simply call 0800 244 838 (anytime between 9am -9pm, 7 days a week).

What will I get?

- Personal Progress Handbook - full of information, practical help and encouragement
- Daily Progress Monitor - tips and advice to help you take it one week at a time
- Helpline Card - access to a confidential helpline service
- Nicorette coin - a useful reminder to 'Think cash not ash'
- 'Relax with Dr Chris Steele' Audio tape - relaxation techniques from a renowned smoking cessation expert
- Regular mailings - tips and advice on health, financial and lifestyle benefits to encourage you to stay stopped
Congratulations on deciding to stop smoking. You've made an important decision and if you're really determined to quit, we can help you through the first few months.

The Nicorette® Fresh Start Complete Quitter's Support Programme is specially designed to give you practical advice on how to quit, as well as help and motivation on the way - and it's completely free!

Call
0800 2 GIVE UP
0800 2 4483 8

for a Fresh Start Support Pack today.
4 mg strength:

Please read this leaflet carefully before you start using this medicine. It provides useful information on how to use it safely. The information applies only to this product. If you have any questions, or you are not sure about anything, please ask your doctor or pharmacist.

REMEMBER: This medicine is for you. Never give it to others. It may harm them even if their symptoms are the same as yours.

What is Nicorette Gum?

Nicorette Peppermint, Ice Mint and Spearmint 4mg Gum:

Each gum contains 4 milligrams of nicotine which is the active ingredient.

Other ingredients are:

- Chewing gum base, xylitol, aspartame, potassium, sodium carbonate, peppermint oil, menthol, salicylic acid, magnesium oxide, quinoline yellow E104 (yellow colour), titanium dioxide E171 (white colour), talc, acacia and carnauba wax.
The chewing gum base contains butylated hydroxy toluene (E321) an anti-oxidant.

None of the gums contain sugar (sucrose) or animal products.

The gums are blister packed in sheets of 6 or 15 and supplied in packs of 12, 15, 30, 105 or 210 pieces. Not all pack sizes may be marketed.

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What is Nicorette Gum used for?

Nicorette Gum is a nicotine replacement therapy (NRT).

It is used to relieve withdrawal symptoms and reduce the cravings for nicotine which people get when they stop smoking or when they are cutting down the number of cigarettes they smoke while trying to stop smoking.

If you smoke more than 20 cigarettes a day, this product will help relieve your cravings.

If you smoke 20 or fewer cigarettes a day, 2mg nicotine gum may be more appropriate.

What does Nicorette Gum do?

When you stop smoking or cut down the number of cigarettes you smoke, your body misses the nicotine that you have been absorbing from the tobacco smoke. You may experience unpleasant feelings and a strong desire to smoke ("craving"). This shows that you were dependent on nicotine. However the toxins in cigarette smoke such as tar, lead, cyanide and ammonia cause smoking related disease and death, rather than nicotine. The benefits of stopping smoking far outweigh any potential risk from using nicotine from NRT.

When you chew Nicorette Gum nicotine is released and passes into your body through the lining of your mouth. The nicotine released from the gum is sufficient to relieve the unpleasant withdrawal symptoms. It will also help to stop the craving to smoke but Nicorette Gum will not give you the "buzz" you get from a cigarette. Make sure you chew Nicorette Gum correctly to get the best effect – see ‘How to chew Nicorette Gum – the Nicorette Chewing Technique’.

As well as the effects of nicotine, you could be very attached to the habit of smoking. For example lighting up after a meal or in certain situations where you are with particular people. These rituals are part of your smoking habit which you may have had for many years. To succeed in giving up you should try to avoid situations where you may be tempted to smoke. Think about the times when you are most likely to miss smoking and try to plan how you will cope on these occasions. Changing your routine will help you to break the habit of smoking.

Encouragement and support from your doctor, nurse, pharmacist, friends and family can make giving up less stressful and more successful. For professional advice about giving up smoking, ask your doctor, nurse or pharmacist.
Do not use Nicorette Gum if:

- you have an allergy to nicotine or any of the other ingredients in your Nicorette Gum.

Before you use Nicorette Gum:

There are some circumstances (listed below) where you should consult your doctor, nurse or pharmacist before using Nicorette Gum:

- If you are pregnant or breast-feeding — as you should try and give up smoking without the use of nicotine replacement therapy. (See “What if you are pregnant or breast-feeding?”)
- If you have heart disease (including heart attack and disorders of heart rate and/or rhythm) or stroke for which you are being treated. In other heart conditions not requiring you to be in hospital, using NRT may be better than continuing to smoke.
- If you have high blood pressure that is not adequately controlled by treatment.
- If you have a stomach or duodenal ulcer and/or inflammation of the oesophagus (passage between the mouth and stomach).
- If you have serious liver or kidney disease.

If you have an over-active thyroid gland or have a phaeochromocytoma (a tumour of the adrenal gland that can affect blood pressure) — your doctor will have told you this.

- If you have diabetes as you should monitor your blood sugar levels more often when starting Nicorette Gum, as you may find your insulin or medication requirements alter.
- If you are taking any other medicines such as theophylline, doxapine or imipramine. Stopping smoking or reducing the number of cigarettes you smoke may require the dose to be adjusted.

Nicorette Gums contain butylated hydroxy toluene (BHT), which may irritate your mouth.

What if you are pregnant or breast-feeding?

Pregnancy

Smoking during pregnancy is associated with risks such as poor growth of the baby before birth, premature birth or stillbirth. Stopping smoking is the single most effective intervention for improving both your health and that of your baby and the earlier smoking stops the better.

Ideally, stopping smoking during pregnancy should be achieved without NRT. However, if you have tried and this is not possible, NRT may be recommended to help as the risk to the developing baby is less than that expected from continued smoking. The decision to use NRT should be made as early on in the pregnancy as possible with the aim of discontinuing use as soon as possible. Products that are taken intermittently may be preferable to nicotine patches. However, patch may be preferred if you have nausea or sickness. Patches, if used, should be removed before going to bed at night.

Breast-feeding

Tobacco smoke produces breathing and other problems in babies and children. If you need to use NRT to help you quit, the amount of nicotine that the baby may receive is considerably smaller and less harmful than the second-hand smoke they would otherwise be breathing in. You are best to use NRT products that are taken intermittently (i.e. not patches) and try to breast-feed at a time just before you take the product to ensure that the baby gets the smallest amount of nicotine possible.

When to use Nicorette Gum and for how long?

Adults over 18 years of age

Because smoking is an addiction you may find it difficult to give up. Some people may find it easier to set a quit date and stop smoking immediately. Others may benefit from gradually reducing the number of cigarettes they smoke each day until they feel able to set a quit date. If you are ready to stop smoking immediately, follow Programme 1. If you are not ready to quit immediately but would rather stop smoking gradually, follow Programme 2.
Dosage instructions

How many pieces should you take:
Most people use around 10 pieces of gum a day. You should not use more than 15 pieces a day. Use only one piece of gum at a time.

How to chew the gum:
Chew it as explained in the section “How to chew Nicorette Gum - the Nicorette Chewing Technique”

<table>
<thead>
<tr>
<th>Programme 1 (Stopping Immediately)</th>
<th>Programme 2 (Stopping Gradually)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step 1: 0 - 3 months</strong></td>
<td><strong>Step 1: 0 - 6 weeks</strong></td>
</tr>
<tr>
<td>Set yourself a quit date when you are not too stressed and ready to stop smoking. Over a period of 3 months use the gum to relieve the cravings to smoke.</td>
<td>Finish how many cigarettes you smoke. Set yourself a date when you decide to reduce the number of cigarettes you smoke. Use Nicorette Gum whenever you feel the urge to smoke and with the intention to reduce your smoking as much as possible. If after 6 weeks you have not managed to reduce the number of cigarettes you smoke, consult your doctor.</td>
</tr>
<tr>
<td><strong>Step 2: Weaning period</strong></td>
<td><strong>Step 2: 6 weeks – 6 months</strong></td>
</tr>
<tr>
<td>After 3 months you should be able to reduce the use of the gum. You should try to use fewer pieces of gum each day. If you are using only one or two pieces per day you should stop completely. However, you should remember that you might feel a sudden craving to smoke long after you’ve given up and you can use the gum again if this should happen.</td>
<td>If you have managed to reduce the number of cigarettes you smoke after 6 weeks, continue to use Nicorette Gum to reduce your smoking progressively until you feel ready to attempt to stop smoking completely. You should aim to stop smoking completely by 6 months. If you have not made a serious attempt to stop smoking completely within 9 months you should speak to your doctor.</td>
</tr>
<tr>
<td>If you need to use the product for longer than 9 months, ask your doctor, nurse or pharmacist for advice.</td>
<td><strong>Step 3: 6 months – 9 months</strong></td>
</tr>
<tr>
<td></td>
<td>When you’re ready to stop smoking completely, cut out all cigarettes and continue to use Nicorette Gum for up to another 9 months to release the craving to smoke.</td>
</tr>
<tr>
<td></td>
<td><strong>Step 4: Weaning period</strong></td>
</tr>
<tr>
<td></td>
<td>3 months after you have stopped smoking completely, you should be able to reduce the use of the gum. You should try to use fewer pieces of gum each day. When you are using only one or two pieces per day, you should stop completely.</td>
</tr>
</tbody>
</table>

Children 12 years and over
Use the number of pieces of gum as recommended for adults. Children 12 years and over should only use NRT for up to 12 weeks. The steps below should be followed when using this product.

**Stopping Immediately (Programme 1)**
**Step 1:** Over an 8 week period try use the gum to relieve the craving to smoke.
**Step 2:** After 8 weeks reduce the use of the gum over the next 4 weeks.
You should try to use fewer pieces of gum each day. When you reduce usage to only 1 or 2 pieces per day you should stop completely.
If you need to use this medicine for longer than 12 weeks, consult your doctor, nurse or pharmacist for advice.

**Stopping Gradually (Programme 2)**
**Stopping gradually is an option if you are unable to stop immediately. However, as the recommended duration of NRT treatment in children 12 years and over is 12 weeks, you should seek advice from your doctor, nurse or pharmacist before using attempting to stop gradually.**

Do not give to children under 12 years.

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**How to chew Nicorette Gum - the Nicorette Chewing Technique**

The method of chewing Nicorette Gum is not the same as for ordinary chewing gum.

Nicorette Gum is chewed to release nicotine than noted so that nicotine can be taken in through the lining of the mouth. If Nicorette Gum is chewed continuously the nicotine is released too quickly and is swallowed. This may irritate your throat, upset your stomach or give you hiccup.

If you have false teeth you may have difficulty chewing the gum as Nicorette Gum could stick to them and on rare occasions, damage dentures. If you experience a problem, other types of nicotine replacement therapy such as a skin patch, inhalator or sublingual tablet may be more suitable for you.

The Nicorette Chewing Technique
1 Chew slowly until taste becomes strong
2 Rest between gum and cheek
3 Chew again when the taste has faded
4 Chew a piece of Nicorette Gum when you feel the urge to smoke.
• Only use one gum at a time and use the Nicorette Chewing Technique.
• Keep chewing like this for about half an hour
• After this time the gum will have lost its strength and you should dispose of it carefully.
• Most people use around 10 pieces of gum a day. You should not use more than 15 pieces a day. Do not exceed the stated dose.

What should you do if you have taken too much Nicorette Gum?
If you have used more than the recommended number of pieces of Nicorette Gum you may experience nausea, salivation, pain in your abdomen, sweating, headache, dizziness, feeling disturbed, or weakness. If any unwanted effects occur contact a doctor or your nearest hospital Accident and Emergency department immediately. If you go to the doctor or hospital, take this leaflet and the pack with you.

What should you do if a child has taken Nicorette Gum?
If a child chews or swallows Nicorette Gum contact a doctor or your nearest hospital immediately. Very rarely abnormal beating of the heart has been reported. If you develop an allergic reaction swelling of the mouth and tongue, itching of the skin, urticaria and inflammation of the lining of the mouth), palpitations, an uneasy (irregular) heartbeat or bad indigestion, stop using the Nicorette Gum, do not smoke and contact a doctor immediately. You may experience some unwanted effects because by stopping smoking you have reduced the amount of nicotine you are taking. These effects are nicotine withdrawal symptoms and include irritability/aggression, feeling low, anxiety, restlessness, poor concentration, increased appetite, weight gain, urges to smoke (‘craving’), night-time awakenings/sleep disturbance and lowering of your heart rate. You may experience nicotine withdrawal symptoms if you use too few pieces of Nicorette Gum before you are ready to reduce your nicotine intake.

When you stop smoking, you may experience mouth ulcers. The reason why this happens is unknown. If you find it difficult to cut down and stop using Nicorette Gum, or are worried that without it you will start smoking again, talk to your doctor, nurse or pharmacist. Remember, Nicorette Gum is not intended as a substitute for smoking, it is an aid to giving up. If you notice these or any other unwanted effects not listed in this leaflet you should tell your doctor, nurse or pharmacist.

Taking care of your Nicorette Gum
Do not use the gum after the ‘Use before’ date on the box or blister strip. Keep Nicorette Gum out of reach and sight of children and pets as nicotine in high doses can be very dangerous and sometimes fatal if taken by small children.
Do not store Nicorette Gum above 25°C. Dispose of Nicorette Gum sensibly.

Are there any unwanted effects from Nicorette Gum?
Like all medicines, Nicorette Gum can have side-effects. These effects are rarely serious. As many of the effects are due to nicotine they can also occur when nicotine is obtained by smoking.
Some unwanted effects you may notice when you start to use Nicorette Gum for the first time include: nicspms, sore throat, increased saliva in your mouth, mild indigestion or heartburn. These effects may be due to using too much Nicorette Gum, chewing it continuously, or swallowing too much nicotine released from the gum. You may also feel sick or faint or get headaches. Please read the chewing instructions again.
Other commonly reported side-effects include dizziness, vomiting, sore mouth or jaw-muscle ache. Chest disturbances, redness or itching of the skin have also occurred but reports of this are uncommon.
UKPAR Nicorette Ice Mint and Spearmint 2 and 4 mg Gum (PL 15513/0143-4 & 152-3)

Helpful Tips on Giving Up

You may have tried to stop smoking before and you know from bitter experience that it's not easy to give up cigarettes. However, you have now taken the first constructive step towards becoming a non-smoker. Overcoming your tobacco dependence you will have to tackle two problems:

1. Your smoking HABIT
2. Your ADDICTION to nicotine

Willpower

The overriding success factor in quitting is how determined you are. The first few weeks of quitting or reducing the number of cigarettes you smoke will probably be the most difficult because your smoking habit is still fresh in your mind. However, you will find that as time goes by, your willpower becomes stronger.

Telling friends, family and work colleagues that you have quit smoking and that you envisage a tough time ahead will encourage them to support you.

1. Pick the right day.
There is never a perfect time to give up smoking, but you should plan ahead by choosing a date in the not too distant future on which you are going to give up cigarettes completely or start reducing the number of cigarettes you smoke. This is your Quit Day. Try to pick a day when you will not be too stressed.

2. Break your routine.
For a number of years you will have become accustomed to smoking at certain times, with particular people or in certain situations. Think about the times you will miss smoking the most and plan how you will cope on these occasions. Changing your routine will help you break the habit of smoking. It may be helpful, if you are reducing the number of cigarettes you are smoking before stopping smoking, to think about how you will reduce the number of cigarettes you smoke and draw up a plan. You may choose to focus on the cigarettes you find least enjoyable and eliminate them first.

3. Quit with a friend.
Quitting with a fellow smoker is a good idea. It will strengthen your resolve and build on your determination. Encourage a friend or family member to quit with you. It will give your morale a boost since there will be another person knowing exactly what you’re feeling and with whom you can share your resolve to quit smoking.

4. Remove any temptation.
When stopping smoking completely, be sure to remove all cigarettes, matches, lighters etc from your home, car and work. Ask your friends and colleagues not to offer you cigarettes or smoke close by you — but be careful not to offend them. Explain that you have given up. This type of support from friends is of greatest benefit for the first couple of weeks of quitting, as this is your most vulnerable time. The last thing you want is a cigarette close at hand in a moment of weakness.

5. Take one day at a time.
When you reach your Quit Day, don’t allow yourself to think that you’re quitting for good. That will make it seem like a superhuman task. Just promise yourself “I won’t have a cigarette today”, and take it one day at a time. You’ll be surprised how much that little thought helps.

6. Distract yourself.
Whenever you feel the urge to smoke coming on, distract yourself by keeping active. Don’t feel sorry for yourself. Get up and DO something. Do that job around the house or garden that you’ve been putting off, or take up a hobby. Remember that the craving only lasts a few minutes.
7 Learn to relax.
Once you have stopped smoking, taking exercise regularly will not only help you get fitter but will encourage you to relax. Exercise has the ability to relieve stress and tension. Taken regularly it will benefit you physically and psychologically. If you haven’t exercised for some time, take it slowly to begin with and increase the amount of time spent exercising over the course of a few weeks. Not only will exercising help you relax but also helps to keep your weight under control, which some people find a problem when quitting.

8 Think cash not ash.
One of the really noticeable benefits of “stopping” is the extra cash that’s suddenly available. To emphasise the point put the money into a pot marked “cash not ash” and watch it accumulate. But be sure to use the money to treat yourself. You deserve a REWARD for NOT smoking.

9 Dealing with relapses.
After you have stopped smoking you might find that in times of stress, reaching for a cigarette is the only thing that will help you through. There may also be certain situations – particularly social situations such as a party or in the pub – where temptation just gets the better of you, so you smoke one or two cigarettes. You might feel that your only option is to go back to smoking. Don’t think of it as having failed, just think through the reasons why you wanted to quit in the first place and don’t let those couple of cigarettes get the better of you. Refer back to your plan and start again. You can beat it!

10 If you don’t succeed.
Giving up is more difficult for some people than others. If you fail to stop first time, don’t be disheartened. Try again at a later date – you CAN do it! Remember the most successful long term ex-smokers have usually had to try several times to stop smoking… if you don’t succeed – quit again.

For further information:
Please read the attached leaflet; “We’ll Help You Make a Fresh Start” which contains details of the Nicorette® Fresh Start Complete Quitters Support Programme.

Date of preparation of this leaflet:
December 2005 ©

Nicorette is a registered trademark.
Nicorette Fresh Start
Complete Quitters Support Programme

How can Fresh Start help me?

Together with your choice of Nicorette, the Fresh Start Programme can greatly increase your chance of success.

As a Fresh Start Committed Quitter we'll send you lots of useful information on stopping smoking, plus encouragement and advice on how you can stay stopped.

Enrolling on the programme couldn't be easier. Simply call 0800 2 44838 (any time between 9am - 9pm, 7 days a week).

What will I get?

- Personal Progress Handbook - full of information, practical help and encouragement
- Daily Progress Monitor - tips and advice to help you take it one week at a time
- Helpline Card - access to a confidential helpline service
- Nicorette coin - a useful reminder "Think cash not ash"
- "Relax with Dr Chris Steele" Audio tape - relaxation techniques from a renowned smoking cessation expert
- Regular mailings - tips and advice on health, financial and lifestyle benefits to encourage you to stay stopped
Congratulations on deciding to stop smoking. You’ve made an important decision and if you’re really determined to quit, we can help you through the first few months.

The Nicorette® Fresh Start Complete Quitter’s Support Programme is specially designed to give you practical advice on how to quit, as well as help and motivation on the way - and it’s completely free!

Call
0800 2 GIVE UP
0800 2 4483 8

for a Fresh Start Support Pack today
UKPAR Nicorette Ice Mint and Spearmint 2 and 4 mg Gum (PL 15513/0143-4 & 152-3)

LABELLING

This product strength is suitable for those smoking 20 cigarettes or less a day.

This pack contains 30 pieces of mint flavour chewing gum, each containing 2 mg nicotine. Also included are chewing gum pieces containing 4 mg nicotine. Each piece contains: nicotine (2 mg or 4 mg), propylene glycol, sorbitol, hypromellose, colour E124, peppermint oil, caramel E150c, magnesium stearate. E102, E142, E160a and citral.

Nicorette 2 mg Gum is for the relief of nicotine withdrawal symptoms as an aid to quitting smoking, it is used to help smokers stop smoking by providing a nicotine replacement therapy which can substitute for the nicotine obtained from smoking.

Low Strength (2 mg)

Use before:

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