NICORETTE FRESHFRUIT 2 and 4 MG GUM

PL  15513/0136-7

UKPAR

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NICORETTE FRESHFRUIT 2 and 4 MG GUM

PL 15513/0136-7

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency granted Pfizer Consumer Health Care Marketing Authorisations (licences) for the medicinal products Nicorette Peppermint 2 and 4 mg Gum (PL 15513/0136-7) 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 Peppermint 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.

These Licences subsequently went through a product name change on 08 December 2006 and are called, ‘Nicorette Freshfruit 2 mg Gum and Nicorette Freshfruit 4 mg Gum’.
NICORETTE FRESHFRUIT 2 and 4 MG GUM

PL 15513/0136-7

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 Peppermint 2 and 4 mg Gum (PL 15513/0136-7) to Pfizer Consumer Health Care. These products hold a GSL.

These national applications for Nicorette Peppermint 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.

These Licences subsequently went through a product name change on 08 December 2006 and are called, ‘Nicorette Freshfruit 2 mg Gum and Nicorette Freshfruit 4 mg Gum’.
PHARMACEUTICAL ASSESSMENT

INTRODUCTION
These are simple national abridged Marketing Authorisation applications for Nicorette Peppermint 2mg Gum and 4 mg Gum (PL 15513/0136-7), 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 Peppermint 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.
NICORETTE FRESHFRUIT 2 and 4 MG GUM

PL  15513/0136-7

**STEPS TAKEN FOR ASSESSMENT**

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<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1</td>
<td>The MHRA received the marketing authorisation application on 11 February 2005</td>
</tr>
<tr>
<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>
</tbody>
</table>
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Nicorette Peppermint 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 Peppermint 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 Peppermint 2mg Gum should be used in conjunction with a behavioural support programme.

4.2 Posology and method of administration
Nicorette Peppermint 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 Peppermint 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 Peppermint 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 Peppermint 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 Peppermint 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 Peppermint 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 Peppermint 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 Peppermint 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 Peppermint 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 Peppermint 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 Peppermint 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 Peppermint 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</td>
<td></td>
<td></td>
</tr>
<tr>
<td>disorders:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac disorders:</td>
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|                  | Very common: | Dizziness                      |
|                  | Common:      | Palpitations                   |
|                  | Uncommon:    | Reversible atrial fibrillation |
Body System | Incidence* | Reported adverse event
---|---|---
Gastrointestinal disorders: | Very common: | Gastrointestinal discomfort, hiccups, nausea
Skin and subcutaneous tissue disorders: | Common: | Vomiting
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 (>1/1 000, <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 Peppermint 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
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 (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 15513/0136

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 Peppermint 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 Peppermint 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 Peppermint 4 mg Gum should be used in conjunction with a behavioural support programme.

4.2. **Posology and method of administration**  
Nicorette Peppermint 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 Peppermint 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 Peppermint 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.

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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 Peppermint 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 Peppermint 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 Peppermint 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 Peppermint 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 Peppermint 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
Peppermint 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 Peppermint 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 Peppermint 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 Peppermint 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:

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<tbody>
<tr>
<td>Nervous system disorders:</td>
<td>Very common</td>
<td>Headache</td>
</tr>
<tr>
<td>Common:</td>
<td></td>
<td>Dizziness</td>
</tr>
<tr>
<td>Cardiac disorders:</td>
<td>Uncommon:</td>
<td>Palpitations</td>
</tr>
<tr>
<td>Very rare:</td>
<td></td>
<td>Reversible atrial fibrillation</td>
</tr>
<tr>
<td>Gastrointestinal disorders:</td>
<td>Very common</td>
<td>Gastrointestinal discomfort,</td>
</tr>
<tr>
<td>Common:</td>
<td></td>
<td>hiccups, nausea</td>
</tr>
<tr>
<td></td>
<td></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

5.1. 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 Peppermint 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 15513/0137

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

10. DATE OF REVISION OF THE TEXT
18/07/2006
UKPAR Nicorette Freshfruit 2 and 4 mg Gum (PL 15513/0136-7)

PATIENT INFORMATION LEAFLET

2 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 2mg Gum:
Each gum contains 2 milligrams of nicotine, which is the active ingredient.
Other ingredients are:
Chewing gum base, xylitol, acacia gum, 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 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.

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.
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.

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/medication requirements after.

If you are taking any other medicines such as theophylline, doxazosine or rilpivirine. 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, 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 about 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'.

### Programme 1 (Stopping Immediately)

<table>
<thead>
<tr>
<th>Step 1: 0 - 3 months</th>
</tr>
</thead>
<tbody>
<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 reduce the craving to smoke.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 2: Weaning period</th>
</tr>
</thead>
<tbody>
<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. When you are using only one or two pieces per day, you should stop completely. However, you should remember that you may feel a sudden craving to smoke long after you've given up and you can use the gum again if this should happen.</td>
</tr>
</tbody>
</table>

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

### Programme 2 (Stopping Gradually)

<table>
<thead>
<tr>
<th>Step 1: 0 - 6 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Establish how many cigarettes you smoke. Set yourself a quit 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. After 6 weeks you may not have managed to reduce the number of cigarettes you smoke, consult your doctor.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 2: 5 weeks - 6 months</th>
</tr>
</thead>
<tbody>
<tr>
<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 6 months, you should seek help from your doctor.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 3: 6 months - 9 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>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 reduce the craving to smoke.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 4: Weaning period</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 months after you have stopped smoking completely, you should still 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 a day, you should stop completely. However, you should remember that you may 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.</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)

<table>
<thead>
<tr>
<th>Step 1: Over an 8 week period try to use the gum to reduce the craving to smoke.</th>
</tr>
</thead>
</table>

| 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 an 8 week period try to use the gum to reduce 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. |

### 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 nutted 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 and give you hiccups.

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 skin patches, inhalators 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, you should 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. Accident and Emergency department. If you go to the doctor or hospital, take this leaflet and the pack with you.

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: hoarseness, 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 swallow 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.

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 unusual (irregular) heart beat 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.
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.

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, 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.

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
gain weight 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.

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 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.
Fresh Start
Complete Quitter 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 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:

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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.

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- 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.

- 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 medication requirements alter.
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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 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 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>Step 1: 0 - 3 months</td>
<td>Step 1: 0 - 3 weeks</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 releive the craving 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.</td>
</tr>
<tr>
<td>Step 2: Weaning period</td>
<td>Step 2: 6 weeks - 6 months</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. 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.</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 made a serious attempt to stop smoking completely within 6 months you should speak to your doctor.</td>
</tr>
<tr>
<td></td>
<td>Step 2: 6 months - 9 months</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>When you are ready to stop smoking completely, cut out all cigarettes and continue to use Nicorette Gum for up to another 9 months to reduce the craving to smoke.</td>
</tr>
<tr>
<td></td>
<td>Step 3: Weaning period</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. 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.</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.

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 nadicin 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 iritate your throat, upset your stomach or give you hicups.

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
• Chew a piece of Nicorette Gum when you feel the urge to smoke.
UKPAR Nicorette Freshfruit 2 and 4 mg Gum (PL 15513/0136-7)

- 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 disturbances, 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 the 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 unsteady (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, urge 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: hiccup, sore throat, increased salvia 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 headache. 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.
1. **Ready the right way.**
   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 you 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.
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.

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 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 4483 8 (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 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
We're here to help

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 4438 8

for a Fresh Start Support Pack today
Annex 1

Reference: PL 15513/0136-0051
PL 15513/0137-0046

Product: Nicorette Freshfruit 2 mg Gum

Marketing Authorisation Holder: McNeil Products Limited

Active Ingredient(s): Nicotine resinate

Reason:
To update, Section 4.1 (Therapeutic indication) of the Summary of Product Characteristics (SmPC) following approval of identical indication for Nicorette Inhalator. Consequential updates are made to Sections 4.2 (Posology and method of administration), 4.3 (Contraindications), 4.6 (Pregnancy and lactation) and 5.1 (Pharmacodynamic properties) of the Summary of Product Characteristics (SmPC), as well as the Patient Information Leaflet (PIL) and the labelling. Additionally, Section 6.6 (Special precautions for disposal) of the SmPC was updated by including ‘Dispose of Nicorette Gum sensibly. Any unused product or waste material should be disposed of in accordance with local requirements’ in line with current guidelines.

Evaluation
The final SmPC fragments, PIL and the labelling are acceptable.

Conclusion
The final granted SmPC fragments, PIL and the labelling are presented below.

Nicorette Freshfruit 2 mg Gum

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
Nicorette Freshfruit 2 mg Gum relieves and/or prevents craving and nicotine withdrawal symptoms associated with tobacco dependence. It is indicated to aid smokers wishing to quit or reduce prior to quitting, to assist smokers who are unwilling or unable to smoke, and as a safer alternative to smoking for smokers and those around them.

Nicorette Freshfruit 2 mg Gum is indicated in pregnant and lactating women making a quit attempt.

4.2 Posology and method of administration
Adults and Children over 12 years of age
Nicorette Freshfruit 2 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, 2 mg nicotine gum is indicated. If more than 20 cigarettes per day are smoked, 4 mg nicotine gum will be needed to meet the withdrawal of the high serum nicotine levels from heavy smoking.
Nicorette Freshfruit 2 mg Gum should be used whenever the urge to smoke is felt or to prevent cravings in situations where these are likely to occur.
Smokers willing or able to stop smoking immediately should initially replace all their cigarettes with the Gum and as soon as they are able, reduce the number of gums used until they have stopped completely.

Smokers aiming to reduce cigarettes should use Nicorette Freshfruit 2 mg Gum, as needed, between smoking episodes to prolong smoke-free intervals and with the intention to reduce smoking as much as possible.

As soon as they are ready smokers should aim to quit smoking completely.

Maximum daily dose: 15 pieces per day.

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Those who have quit smoking, but are having difficulty discontinuing Nicorette Freshfruit 2 mg Gum are recommended to contact their pharmacist or doctor for advice.

For those using the 4 mg gum, switching to the 2 mg gum may be helpful when stopping treatment or reducing the number of gums used each day.

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

### 4.3 Contraindications

Hypersensitivity to nicotine or any component of the chewing gum.

Nicorette Freshfruit 2 mg Gum is contraindicated in children under the age of 12 years.

### 4.6 Fertility, pregnancy and lactation

**Pregnancy**

Stopping smoking is the single most effective intervention for improving the health of both the pregnant smoker and her baby, and the earlier abstinence is achieved the better. Ideally smoking cessation during pregnancy should be achieved without NRT. However, if the mother cannot (or is considered unlikely to) quit without pharmacological support, NRT may be used as the risk to the fetus is lower than that expected with smoking tobacco. Stopping completely is by far the best option but if this is not achievable Nicorette Freshfruit 2 mg Gum may be used in pregnancy as a safer alternative to smoking. Because of the potential for nicotine-free periods, intermittent dose forms are preferable, but patches may be necessary if there is significant nausea and/or vomiting. If patches are used they should, if possible, be removed at night when the fetus would not normally be exposed to nicotine.
Lactation
The relatively small amounts of nicotine found in breast milk during NRT use are less hazardous to the infant than second-hand smoke. Intermittent dose forms would minimize the amount of nicotine in breast milk and permit feeding when levels were at their lowest.

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 Freshfruit 2 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.

Increased appetite is a recognised symptom of nicotine withdrawal and post-cessation weight gain is common. Clinical trials have demonstrated that Nicotine Replacement Therapy can help control weight following a quit attempt.

6.6 Special precautions for disposal
Dispose of Nicorette Gum sensibly.

Any unused product or waste material should be disposed of in accordance with local requirements.

Nicorette Freshfruit 4 mg Gum

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
Nicorette Freshfruit 4 mg Gum relieves and/or prevents craving and nicotine withdrawal symptoms associated with tobacco dependence. It is indicated to aid smokers wishing to quit or reduce prior to quitting, to assist smokers who are unwilling or unable to smoke, and as a safer alternative to smoking for smokers and those around them.

Nicorette Freshfruit 4 mg Gum is indicated in pregnant and lactating women making a quit attempt.

4.2 Posology and method of administration
Adults and Children over 12 years of age

Nicorette Freshfruit 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, 2 mg nicotine gum is indicated. If more than 20 cigarettes per day are smoked, 4 mg nicotine gum will be needed to meet the withdrawal of the high serum nicotine levels from heavy smoking.

Nicorette Freshfruit 4 mg Gum should be used whenever the urge to smoke is felt or to prevent cravings in situations where these are likely to occur.

Smokers willing or able to stop smoking immediately should initially replace all their cigarettes with the Gum and as soon as they are able, reduce the number of gums used until they have stopped completely.

Smokers aiming to reduce cigarettes should use Nicorette Freshfruit 4 mg Gum, as needed, between smoking episodes to prolong smoke-free intervals and with the intention to reduce smoking as much as possible.

As soon as they are ready smokers should aim to quit smoking completely.

Maximum daily dose: 15 pieces per day.

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Those who have quit smoking, but are having difficulty discontinuing Nicorette Freshfruit 4 mg Gum are recommended to contact their pharmacist or doctor for advice.

For those using the 4mg gum, switching to the 2 mg gum may be helpful when stopping treatment or reducing the number of gums used each day.

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

4.3 **Contraindications**

Hypersensitivity to nicotine or any component of the chewing gum.

Nicorette Freshfruit 4 mg Gum is contraindicated in children under the age of 12 years.

4.6 **Pregnancy and lactation**

*Pregnancy*

Stopping smoking is the single most effective intervention for improving the health of both the pregnant smoker and her baby, and the earlier abstinence is achieved the better. Ideally smoking cessation during pregnancy should be achieved without NRT. However, if the mother cannot (or is considered unlikely to) quit without pharmacological support, NRT may be used as the risk to the fetus is lower than that expected with smoking tobacco. Stopping
completely is by far the best option but if this is not achievable Nicorette Freshfruit 4 mg Gum may be used in pregnancy as a safer alternative to smoking. Because of the potential for nicotine-free periods, intermittent dose forms are preferable, but patches may be necessary if there is significant nausea and/or vomiting. If patches are used they should, if possible, be removed at night when the fetus would not normally be exposed to nicotine.

**Lactation**

The relatively small amounts of nicotine found in breast milk during NRT use are less hazardous to the infant than second-hand smoke. Intermittent dose forms would minimize the amount of nicotine in breast milk and permit feeding when levels were at their lowest.

### 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 Freshfruit 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.

Increased appetite is a recognised symptom of nicotine withdrawal and post-cessation weight gain is common. Clinical trials have demonstrated that Nicotine Replacement Therapy can help control weight following a quit attempt.

#### 6.6 Special precautions for disposal

Dispose of Nicorette Gum sensibly.

Any unused product or waste material should be disposed of in accordance with local requirements.
UKPAR Nicorette Freshfruit 2 and 4 mg Gum (PL 15513/0136-7)

1 What the medicine is for
Nicorette Gum is a nicotine replacement therapy (NRT). It is used to relieve and/or prevent withdrawal symptoms and reduce the cravings for nicotine that you get when you try to stop smoking, or when cutting down the number of cigarettes you smoke trying to stop smoking.

Nicorette Gum can also be used when you are pregnant or breast-feeding to help you stop smoking, as the risks to your baby are far less than if you continue to smoke.

For more information, see "If you are pregnant or breast-feeding" section.

Adults should always aim to stop smoking.

You can use Nicorette Gum to achieve this by using it to completely replace all your cigarettes.

However Nicorette Gum can also be used in other ways:

- If you feel unable to stop smoking completely, or if you cannot replace certain cigarettes and therefore it can help you to cut down the number of cigarettes you smoke.
- At those times when you can’t or do not want to smoke, for example:
  - Where you don’t want to smoke and avoid harm to other e.g. children or family.
  - Smoke free areas e.g. Pub, public transport e.g. aeroplanes.

It may also help increase your motivation to quit.

When making a quit attempt a behavioural support programme will increase your chances of success.

Details of Nicorette ActiveStop at the end of this leaflet.

If you smoke 20 or fewer cigarettes a day, the 2 mg nicotine gum will help relieve your cravings. If you smoke more than 20 cigarettes a day, the 4 mg nicotine gum may be more appropriate.

What does Nicorette Gum do?

When you stop smoking, it will help cut down the number of cigarettes you smoke, your body misses the nicotine that you have been absorbing. You may experience unpleasant feelings and a strong desire to smoke (crying). This indicates that you were dependent on nicotine.

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 smoking a cigarette. Benefits you can get from using NRT instead of smoking.

For the best effect, make sure you chew Nicorette Gum correctly. See "How to chew Nicorette Gum - the Nicorette Chewing Technique".

The benefits of stopping smoking far outweigh any potential risk from using nicotine from NRT. It is the toxins in cigarette smoke such as tar, lead, nicotine, cadmium and ammonia that cause smoking related disease and death, not the nicotine.

You may think that smoking helps relieve feelings of anxiety and stress, but it does not deal with the cause of the stress and leads to a number of serious diseases. In addition, the feeling of relaxation after smoking is temporary, with withdrawal symptoms and cravings soon returning.

Nicotine replacement therapy can help relieve nicotine withdrawal symptoms such as irritability, low mood, anxiety, restlessness and cravings when used in place of cigarettes.

NRT may benefit smokers who want to quit, by helping to control weight gain that may be experienced when trying to stop smoking.

Use of NRT is safer than smoking tobacco but as soon as you are ready, you should aim to stop smoking completely.

2 Before using this medicine

Do not use Nicorette Gum:

- If you have difficulty in breathing or of any of the other ingredients.

Talk to your doctor, nurse or pharmacist:

- If you are pregnant or breast-feeding – you may be able to use nicotine replacement therapy (NRT) to help you give up smoking but you should try to give up without it. See "If you are pregnant or breast-feeding" section.

- If you have a heart attack, because of heart disease (including heart attack, disorders of heart rate or rhythm, high blood pressure in other heart conditions not requiring you to be on NRT), you should try to give up smoking.

- If you have a stomach ulcer, looseness diarrhoea, irritation of the mouth or gagging from the nicotine gum, bad breath or inflammation of the mouth or tongue.

- If you have liver or kidney disease.

If you have an overactive 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 – your doctor will have told you this.

If you are taking other medicines such as sympathomimetics, e.g. ephedrine, adrenaline or amphetamines. Stopping smoking or cutting down may require the dose of these medicines to be adjusted.

If any of these applies, talk to your doctor, nurse or pharmacist.

Some of the ingredients in Nicorette Gum can cause problems

Nicorette Gum contains butylated hydroxytoluene (E321), an antioxidant, which may irritate your mouth.

If you are pregnant or breast-feeding

If you are pregnant:

1. Firstly, you should try to give up smoking without NRT. Stopping completely is by far the best option. The earlier and quicker you do this the better it is for you and your baby.

2. Secondly, if you cannot manage this, you can use NRT as a safer alternative to smoking as the risks to your baby are far less than smoking, however you should talk to your doctor, nurse or pharmacist for advice.

Products that are used intermittently, including nicotine gum may be preferable to nicotine patches. However, patches may be more suitable if you have nausea or sickness. If you do use patches take them off before going to bed at night.

If you are breast-feeding:

1. Firstly, you should try to give up smoking without NRT.

2. Secondly, if you can’t manage this you are best to use NRT products that are taken intermittently (not patches), however you should talk to your doctor, nurse or pharmacist for advice. Breast-feed just before you use nicotine gum to ensure that the baby gets the smallest amount of nicotine possible.

If you do 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 inhale if you smoked tobacco. Tobacco smoke produces breathing and other problems in babies and children.

3 How and when to use this medicine

When to use Nicorette Gum

The table below contains the dosage information for Nicorette Gum. This shows the number of gums you should be using, when you should take them.

Please read this information carefully and then go to the "How to stop smoking: your choice" section, which will then decide which method to use to give up smoking.

Use the "How to chew Nicorette Gum – the Nicorette Chewing Technique" instructions which follow. The method of chewing is NOT the same as that for ordinary chewing gum.

This way of chewing ensures that the nicotine is correctly released from the gum.

The number of Nicorette Gums you use each day will depend on how many cigarettes you smoked and how strong they are. See the dosing table to find out the dose you should take.

The 2 mg gums should be used by people who smoke 20 or fewer cigarettes each day or by heavier smokers when they are cutting down the number and strength of the Nicorette Gums they are using.

The 4 mg gums should be used by people who smoke more than 26 cigarettes each day.

Children under 12 years

Do not give this product to children under 12 years.

Adults and Children 12 years and over

Number of cigarettes you smoke per day

<table>
<thead>
<tr>
<th>Number of cigarettes you smoke per day</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
</tr>
<tr>
<td>10</td>
</tr>
<tr>
<td>20</td>
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<td>20 and more</td>
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Use only one piece of gum at a time.

The frequency with which you use the gum will depend on how many cigarettes you smoked and how strong they were.

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 coated 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 mouth, upset your stomach or give you hiccups.

If you have difficulty chewing the gum as Nicorette Gum could stick to the roof of your mouth and cause these symptoms.

If you experience a problem, other types of nicotine replacement therapy such as a skin patch, inhalator or microtub 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.

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.
UKPAR Nicorette Freshfruit 2 and 4 mg Gum (PL 15513/0136-7)

How to stop smoking:
If you are able to stop smoking you should use nicotine gum, when needed, in place of cigarettes. As soon as you can this could be after a number of weeks or months you should replace the number of gums you use until you have stopped using them completely.
If you are unable to stop smoking or do not feel ready to quit at this time, you should replace as many cigarettes as possible with nicotine gum.
There are toxins in cigarettes that can cause harm to your body. Nicorette gum provides a safer alternative to smoking, for both you and those around you. Reducing the number of cigarettes may also help you to become more motivated to stop smoking. As soon as you are ready you should aim to stop smoking completely.
You can also use nicotine gum on those occasions when you can’t or don’t want to smoke, e.g. social situations such as a party, in the pub or when at work.
When making a quit attempt, behavioral therapy, advice and support will normally improve the success rate. If you have quit smoking and want to stop using nicotine gum but are finding it difficult to do so, you should contact your doctor, nurse or pharmacist for advice.

Because smoking is an addiction, you may feel it difficult to give up, from time to time you may still have strong urges to smoke but if you follow these recommendations, you have a good chance of quitting.
Some people may find it easier to set a quit date.

If you have used too many gums:
If you have used more than the recommended dosage you may experience nausea (feeling sick), salivation, pain in your abdomen, diarrhoea, sweating, headache, dizziness, hearing disturbance or weakness.
If you do get any of these effects contact a doctor or your nearest hospital Accident and Emergency department immediately. Take the leaflet and the pack with you.

If a child has used or swallowed the gums:
Contact a doctor or your nearest hospital Accident and Emergency department immediately. If a child under 12 years uses, chews or swallows this medicine. Take the leaflet and the pack with you.
Nicotine ingestion by a child may result in severe poisoning.

Possible side-effects
Like all medicines, Nicorette Gum can have side-effects. As many of the effects are due to nicotine, they can also occur when nicotine is obtained by smoking.
Effects related to stopping smoking (one of the withdrawal symptoms):
You may experience unwanted effects because by stopping smoking you have reduced the amount of nicotine you are taking. You may also experience these effects if you under use Nicorette Gum before you are ready to reduce your nicotine intake.
These effects include:
-  instability or aggression
-  feeling low
-  anxiety
-  restlessness
-  poor concentration
-  increased appetite or weight gain
-  urges to smoke (craving)
-  night time awakening or deep disturbance
-  lowering of heart rate

Effects of too much nicotine
You may also get these effects if you are not used to inhaling tobacco smoke.

These effects include:
-  feeling faint
-  feeling sick (nausea)
-  headache
-  hiccuping (due to excessive swallowing of nicotine)

Side-effects of Nicorette Gum
Nicorette Gum can sometimes cause a slight irritation of the throat at the start of the treatment. It may also cause increased salivation.
Those who suffer from indigestion may suffer from heartburn or indigestion and may benefit from slower chewing and use of the 2 mg gum.
Also use new line for subsequent sentences.
The gum may occasionally stick to dentures and in rare cases damage them.

Very common side-effects
(more than 1 in every 10 people are affected):
-  headache
-  sore mouth or throat
-  jaw muscle ache
-  stomach discomfort
-  feeling sick (nausea)
-  hiccup

Common side-effects
(less than 1 in every 10 people are affected):
-  dizziness
-  sickness (vomiting)

Uncommon side-effect
(less than 1 in every 100 people are affected):
-  hives
-  reddening or itching of the skin
-  chest palpitations

Rare: side-effects
(less than 1 in 1,000 people are affected):
-  allergic reactions (swelling of the mouth, lips, throat and tongue, itching of the skin, swelling of skin, irritation and inflammation of the lining of the mouth)

Very rare side-effects
(less than 1 in 10,000 people are affected):
-  abnormal beating of the heart
-  if you notice these or any other unwanted effects not listed in this leaflet tell your doctor, nurse or pharmacist.

When you stop smoking you may also develop mouth ulcers. The reason why this happens is unknown.

Storing and disposal
Keep Nicorette Gum out of reach and sight of children and animals. Nicotine in high doses can be very dangerous and sometimes fatal if taken by small children.
Do not store Nicorette Gum above 25°C.
Do not use the gum after the ‘Use before’ date on the box or blister strip.
Dispose of Nicorette Gum sensibly.
Medicines should not be disposed of via water or household waste. Ask your pharmacist how to dispose of medicines no longer required.
These measures will help to protect the environment.

Further information
What’s in this medicine?
The active ingredient in Nicorette Freshfruit 2 mg Gum is nicotine.
Other ingredients are: chewing gum base, sucrose, anhydrous sodium carbonate, calcium hydrogen phosphate, colour E151, E162, acacia, gum arabic, gellan gum, gum tragacanth, xanthan gum, sodium benzoate, pectin.

Who makes Nicorette Gum?
The Product Licence holder is McColl Products Ltd, Maidhead, Berks, SL6 8UW, UK.
The manufacturer is McNeil AB, Helsingborg, Sweden.
This leaflet was revised in June 2015.

Information about Nicorette ActiveStop
Nicorette ActiveStop is a personalisation support programme which works with Nicorette to support you with the aim of helping you give up smoking.
All you need is internet access.
Call 0800 244 838 for information.
UKPAR Nicorette Freshfruit 2 and 4 mg Gum (PL 15513/0136-7)