NiQuitin 2 mg Lozenges
PL 00079/0606

NiQuitin 4 mg Lozenges
PL 00079/0607

UKPAR

TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lay Summary</td>
<td>2</td>
</tr>
<tr>
<td>Scientific discussion</td>
<td>3</td>
</tr>
<tr>
<td>Steps taken for assessment</td>
<td>10</td>
</tr>
<tr>
<td>Steps taken after authorisation – summary</td>
<td>11</td>
</tr>
<tr>
<td>Summary of Product Characteristics</td>
<td>12</td>
</tr>
<tr>
<td>Product Information Leaflet</td>
<td>28</td>
</tr>
<tr>
<td>Labelling</td>
<td>32</td>
</tr>
</tbody>
</table>
NiQuitin 2 mg Lozenges
PL 00079/0606

NiQuitin 4 mg Lozenges
PL 00079/0607

LAY SUMMARY

The MHRA granted Beecham Group PLC Marketing Authorisations (licences) for the medicinal products NiQuitin 2mg Lozenges and NiQuitin 4mg Lozenges on 29th March 2007. These products to be available on General sale list (GSL). NiQuitin Lozenges are a stop smoking aid. They can help you give up smoking straightaway or cut down smoking before stopping completely.

NiQuitin Lozenges contain a nicotine resin and when sucked, nicotine is released slowly from the resin and absorbed through the lining of the mouth. This nicotine relieves some of the unpleasant symptoms, such as feeling ill or irritable, that smokers often feel when they try to give up or when they are in situations where they cannot have a cigarette. The nicotine can also reduce your cravings for a cigarette and help you to resist the urge to smoke.

These applications are duplicates of previously granted applications for NiQuitin CQ 2mg Lozenge and NiQuitin CQ 4mg Lozenge (PL 00079/0369-70), for which the marketing authorisation holder is Beecham Group plc and which was granted on 24th September 2001.

No new or unexpected safety concerns arose from these simple applications and it was, therefore, judged that the benefits of taking NiQuitin Lozenges outweigh the risks, hence Marketing Authorisations have been granted.
NiQuitin 2 mg Lozenges  
PL 00079/0606

NiQuitin 4 mg Lozenges  
PL 00079/0607

SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

Introduction .................................................................................. Page 4
Pharmaceutical assessment .......................................................... Page 5
Preclinical assessment .................................................................. Page 7
Clinical assessment ....................................................................... Page 8
Overall conclusions and risk benefit assessment ............................ Page 9
INTRODUCTION

The UK granted marketing authorisations for the medicinal products NiQuitin 2mg Lozenges and NiQuitin 4mg Lozenges (PL 00079/0606-7) to Beecham Group PLC on 29th March 2007. The products are available as General Sale List (GSL).

The applications were submitted as simple abridged applications according to Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC, cross-referring to NiQuitin CQ 2mg and 4mg Lozenges (PL 00079/0369-70).

NiQuitin Lozenges are indicated for the treatment of tobacco dependence by relief of nicotine withdrawal symptoms including cravings. Permanent cessation of tobacco use is the eventual objective. NiQuitin Lozenges can be used:

- for smoking cessation (abrupt and gradual).
- as an aid for smokers during temporary abstinence.

NiQuitin Lozenges should preferably be used in conjunction with a behavioral support programme.

NiQuitin Lozenges work by replacing some of the nicotine you are used to getting from cigarettes. It is the nicotine in cigarettes that can make you physically addicted to them. This type of treatment is called Nicotine Replacement Therapy (NRT).

No new data was submitted nor was it necessary for these simple applications, as the data are identical to that of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no PAR was generated for it.
PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 00079/0606-7
PROPRIETARY NAME: NiQuitin 2mg and 4mg Lozenge
ACTIVE(S): Nicotine Polacrilex
COMPANY NAME: Beecham Group PLC
LEGAL STATUS: GSL

1. INTRODUCTION
This is a simple, piggy back application for NiQuitin 2mg and 4mg Lozenge submitted under Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC. The proposed MA holder is Beecham Group plc, 980 Great West ROAD, Brentford, Middlesex, TW8 9GS, UK.

The applications cross-refer to NiQuitin CQ 2mg and 4mg Lozenges (PL 00079/0369-70), approved on 24th September 2001 to the marketing authorisation holder Beecham Group PLC. The current applications are considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM
2.1 Name(s)
The proposed names of the products are NiQuitin 2 mg Lozenges and NiQuitin 4 mg Lozenges. The products have been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
The products contain 11.1 and 22.2 mg nicotine polacrilex, equivalent to 2 and 4 mg nicotine. It is to be stored in a Clear or opaque Polyvinyl Chloride, Polyethylene and Polyvinylidene Chloride blisters. The proposed shelf-life (3 years) and storage conditions (Do not store above 25 degrees and store in the original package) are consistent with the details registered for the cross-reference product.

2.3 Legal status
On approval, the products will be available as General Sale List (GSL).

2.4 Marketing authorisation holder/Contact Persons/Company
Beecham Group plc, 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom

The QP responsible for pharmacovigilance is stated and his CV is included.

2.5 Manufacturers
The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition
The proposed composition is consistent with the details registered for the cross-reference product.
2.7 Manufacturing process
The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size is stated.

2.8 Finished product/shelf-life specification
The proposed finished product specifications are in line with the details registered for the cross-reference products.

2.9 Drug substance specification
The proposed drug substance specifications are consistent with the details registered for the cross-reference products.

2.10 TSE Compliance
No materials of animal or human origin are included in the products. This is consistent with the cross reference product.

3. EXPERT REPORTS
The applicant has included detailed expert reports in Module 2 of the application. Signed declarations and copies of the experts’ CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product name. The appearance of the product is identical to the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS
The proposed summary is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET/CARTON
The patient information leaflet has been prepared in-line with the details registered for the cross-reference product.

Carton and blister
The proposed artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements.

7. CONCLUSIONS
The data submitted with the applications are acceptable. Marketing Authorisations should be granted.
PRECLINICAL ASSESSMENT

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

No new clinical data have been supplied and none are required.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

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

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

EFFICACY
These applications are identical to previously granted applications for NiQuitin CG 2mg Lozenge and NiQuitin CG 4mg Lozenge (PL 00079/0369 and PL 00079/0370).

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 product.

RISK BENEFIT ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant’s product is identical to the cross-reference product. Extensive clinical experience with NiQuitin Lozenge is considered to have demonstrated the therapeutic value of the compound. The risk:benefit is, therefore, considered to be positive.
NiQuitin 2 mg Lozenges  
PL 00079/0606  

NiQuitin 4 mg Lozenges  
PL 00079/0607  

STEPS TAKEN FOR ASSESSMENT

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
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<tr>
<td>1</td>
<td>The MHRA received the marketing authorisation applications on 02/05/2006.</td>
</tr>
<tr>
<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 09/06/2006.</td>
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<tr>
<td>3</td>
<td>Following assessment of the application the MHRA requested further information on 26/09/2002 and 07/09/2006.</td>
</tr>
<tr>
<td>4</td>
<td>The applicant responded to the MHRA’s requests, providing further information on 28/10/2006</td>
</tr>
<tr>
<td>5</td>
<td>The application was determined on 29/03/2007</td>
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</tbody>
</table>
### STEPS TAKEN AFTER ASSESSMENT

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<th>Application type</th>
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<td>11/06/2007</td>
<td>Type II Medical</td>
<td>To update sections of SPC</td>
<td>17/09/2007 Approved</td>
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<tr>
<td>14/09/2007</td>
<td>Type II Medical</td>
<td>To reduce the frequency of the PSUR submission cycle to a 3 yearly submission cycle.</td>
<td>09/10/2007 Approved</td>
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</tbody>
</table>
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
NiQuitin 2 mg Lozenges

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each lozenge contains 2 mg nicotine (as 11.1 mg nicotine polacrilex). For excipients see Section 6.1.

3 PHARMACEUTICAL FORM
Lozenge
White, round lozenge with convex surfaces, debossed NL2 on one side.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications
NiQuitin Lozenges are indicated for the treatment of tobacco dependence by relief of nicotine withdrawal symptoms including cravings. Permanent cessation of tobacco use is the eventual objective. NiQuitin Lozenges can be used:

- for smoking cessation (abrupt and gradual).
- as an aid for smokers during temporary abstinence.

NiQuitin Lozenges should preferably be used in conjunction with a behavioral support programme.

4.2 Posology and method of administration

*Directions for use:*

NiQuitin 2 mg Lozenges are suitable for smokers who have their first cigarette of the day more than 30 minutes after waking up.

One lozenge should be placed in the mouth and allowed to dissolve. Periodically, the lozenge should be moved from one side of the mouth to the other, and repeated, until the lozenge is completely dissolved (approximately 20 – 30 minutes). The lozenge should not be chewed or swallowed whole.

Users should not eat or drink while a lozenge is in the mouth.

Behavioural therapy, advice and support will normally improve the success rate.
Adults (18 years and over):

**Abrupt cessation of smoking:**

Users should make every effort to stop smoking completely during treatment with NiQuitin Lozenges.

Recommended treatment schedule:

<table>
<thead>
<tr>
<th>Step 1 Weeks 1 to 6</th>
<th>Step 2 Weeks 7 to 9</th>
<th>Step 3 Weeks 10 to 12</th>
</tr>
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<tr>
<td>Initial treatment period</td>
<td>Step down treatment period</td>
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</tr>
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<td>1 lozenge every 1 to 2 hours</td>
<td>1 lozenge every 2 to 4 hours</td>
<td>1 lozenge every 4 to 8 hours</td>
</tr>
</tbody>
</table>

During weeks 1 to 6 it is recommended that users take a minimum of 9 lozenges per day. Users should not exceed 15 lozenges per day.

To help stay smoke free beyond 12 weeks, users may take 1-2 lozenges per day only on occasions when they are strongly tempted to smoke.

Those who use the lozenges beyond 9 months are recommended to seek additional help and advice from a healthcare professional.

**Gradual cessation of smoking:**

For smokers who are unwilling or unable to quit abruptly.

Use a lozenge whenever there is a strong urge to smoke in order to reduce the number of cigarettes smoked as far as possible and to refrain from smoking as long as possible.

The number of lozenges a day is variable and depends on the patients needs. Nonetheless it should not exceed 15 lozenges per day.

If a reduction in cigarette consumption has not been achieved after 6 weeks of treatment, a healthcare professional should be consulted.

Reduced tobacco consumption should lead to complete cessation of smoking. This should be attempted as soon as possible. When the number of cigarettes has been reduced to a level from which the user feels able to quit completely, then start on the schedule for “abrupt cessation” as given above.

If an attempt to stop smoking completely has not been started within 6 months after the beginning of treatment, it is recommended to consult a healthcare professional.

**Temporary abstinence:**

Use a lozenge every 1-2 hours to control troublesome withdrawal symptoms including cravings. Users should not take more than 15 lozenges per day.
Users should be encouraged to stop smoking completely as soon as possible. If users are still feeling the need to use lozenges on a regular basis 6 months after the start of treatment and have still been unable to undertake a permanent quit attempt, then it is recommended to seek additional help and advice from a healthcare professional.

**Adolescents and children:**

Adolescents (12-17 years) should follow the schedule of treatment for abrupt cessation of smoking as given above, but as data are limited, duration of NRT in this age group is restricted to 12 weeks. If longer treatment is required, or where adolescents are unwilling or unable to quit smoking abruptly, advice from a healthcare professional should be sought.

NiQuitin Lozenges are not recommended for use in children under 12 years of age.

**4.3 Contraindications**

NiQuitin Lozenges are contraindicated in:

- those with hypersensitivity to nicotine or any of the excipients;
- children under the age of 12 years and non-smokers.

**4.4 Special warnings and precautions for use**

The risks associated with the use of NRT are substantially outweighed in virtually all circumstances by the well established dangers of continued smoking.

_Patients hospitalised for MI, severe dysrhythmia or CVA_ who are considered to be haemodynamically unstable should be encouraged to stop smoking with non-pharmacological interventions. If this fails, NiQuitin Lozenges may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision. Once patients are discharged from hospital they can use NRT as normal.

_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.

_Allergic reactions:_ Susceptibility to angioedema and urticaria

A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions:

- _Renal and hepatic impairment:_ Use 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.
- _Phaeochromocytoma and uncontrolled hyperthyroidism:_ Use with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma as nicotine causes release of catecholamines.
- _GI disease:_ Swallowed nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastric or peptic ulcers and oral NRT preparations should be used with caution in these conditions. Ulcerative stomatitis has been reported.

_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.
**Stopping smoking:** Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs catalysed by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops this may result in a slower metabolism and a consequent rise in blood levels of such drugs.

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

**Phenylketonuria:** NiQuitin Lozenges are sugar free, but do contain aspartame which metabolises to phenylalanine, which is of relevance for those with phenylketonuria.

**Sodium content:** Each NiQuitin Lozenge contains 15 mg of sodium. People on a low sodium diet should take this into account.

### 4.5 Interaction 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.

### 4.6 Pregnancy and lactation

**Pregnancy**

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. 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.

However, as nicotine passes to the fetus affecting breathing movements and has a dose dependent effect on placental/fetal circulation, the decision to use NRT should be made as early on in the pregnancy as possible. The aim should be to use NRT for only 2-3 months.

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**

Nicotine from smoking and NRT is found in breast milk. However the amount of nicotine the infant is exposed to from NRT 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

NRT can cause adverse reactions similar to those associated with nicotine administered in other ways including smoking. These may be attributed to the pharmacological effects of nicotine, some of which are dose dependent. At recommended doses NiQuitin Lozenges have not been found to
cause any serious adverse effects. Excessive consumption of NiQuitin Lozenges by those who have not been in the habit of inhaling tobacco smoke could possibly lead to nausea, faintness or headaches.

Certain symptoms which have been reported such as depression, irritability, anxiety and insomnia may be related to withdrawal symptoms associated with smoking cessation. Subjects quitting smoking by any means could expect to suffer from headache, dizziness, sleep disturbance, increased coughing or a cold.

**Related adverse events with excess in active compared to placebo group in a controlled study.**

**Platelet bleeding and clotting disorders**
- Uncommon >1/1000; <1/100: gingival bleeding; nosebleed

**Psychiatric disorders**
- Common >1/100; <1/10: insomnia; anxiety; irritability; increased appetite
- Uncommon >1/1000; <1/100: anger; aggravated anxiety; abnormal dreaming; abnormal hunger; mood swings; wakefulness

**Central and peripheral nervous system disorders**
- Common >1/100; <1/10: headache
- Uncommon >1/1000; <1/100: lightheaded feeling; localised numbness

**Heart rate and rhythm disorders**
- Uncommon >1/1000; <1/100: aggravated palpitations; palpitations; tachycardia

**Vascular (extracardiac) disorders**
- Uncommon >1/1000; <1/100: vascular disorder; flushing; skin flushed

**Respiratory system disorders**
- Common >1/100; <1/10: pharyngitis
- Uncommon >1/1000; <1/100: laryngismus; aggravated asthma; lower respiratory tract infection; coughing; nasal irritation; throat irritation; nasal congestion

**Gastrointestinal system disorders**
- Very common >1/10: nausea
- Common >1/100; <1/10: vomiting; dyspepsia, heartburn, indigestion; hiccups; mouth irritation, mouth ulceration; tongue ulceration; diarrhoea; belching; flatulence
- Uncommon >1/1000; <1/100: peptic ulcer; dysphagia; aggravated dyspepsia; gastroesophageal reflux; hiatus hernia; oesophagitis; eructation; buccal mucosal ulceration; borborygmus; dry lips; dry throat; tongue disorder; tooth ache

**Special senses other, disorders**
- Uncommon >1/1000; <1/100: parageusia, metallic taste; taste perversion

**Skin and appendages disorders**
- Uncommon >1/1000; <1/100: erythema; itching; rash; skin reaction localised; increased
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 with oxygen should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: N07B A01

Nicotine is an agonist at nicotine receptors in the peripheral and central nervous system and has pronounced CNS and cardiovascular effects. When consumed in tobacco products, it has been shown to be addictive and abstinence is linked to craving and withdrawal symptoms. These craving and withdrawal symptoms include urge to smoke, depressed mood, insomnia, irritability, frustration or anger, anxiety, difficulty in concentrating, restlessness and increased appetite or weight gain. The lozenges replace some of the nicotine provided by tobacco and help reduce the severity of these nicotine craving and withdrawal symptoms.

5.2 Pharmacokinetic properties

NiQuitin Lozenges completely dissolve in the oral cavity, and the entire amount of nicotine contained in the lozenge becomes available for buccal absorption or ingestion (swallowing). The complete dissolution of NiQuitin Lozenge is typically achieved in 20-30 minutes. The peak plasma concentrations of nicotine achieved after a single dose are approximately 4.4 ng/ml. When dosed every 1.5 hours, the steady state peak and trough concentrations are 12.7 and 9.4 ng/ml respectively. Ingestion of NiQuitin Lozenges not following dosing instructions (chewed, retained in the mouth, and swallowed; chewed and immediately swallowed) does not result in faster or higher absorption, but a substantial amount of nicotine (80-93%) is still absorbed.

As the plasma protein binding of nicotine is low (4.9% - 20%), the volume of distribution of nicotine is large (2.5 l/kg). The distribution of nicotine to tissue is pH dependent, with the highest concentrations of nicotine found in the brain, stomach, kidney and liver.

Nicotine is extensively metabolized to a number of metabolites, all of which are less active than the parent compound. The metabolism of nicotine primarily occurs in the liver, but also in the lung and kidney. Nicotine is metabolized primarily to cotinine but is also metabolized to nicotine N'-oxide. Cotinine has a half-life of 15-20 hours and its blood levels are 10 times higher than nicotine. Cotinine is further oxidized to trans-3'-hydroxycotinine, which is the most abundant metabolite of nicotine in the urine. Both nicotine and cotinine undergo glucuronidation.
The elimination half-life of nicotine is approximately 2 hours (range 1 - 4 hours). Total clearance for nicotine ranges from approximately 62 to 89 l/hr. Non-renal clearance for nicotine is estimated to be about 75% of total clearance. Nicotine and its metabolites are excreted almost exclusively in the urine. The renal excretion of unchanged nicotine is highly dependent on urinary pH, with greater excretion occurring at acidic pH.

5.3 Preclinical safety data
The general toxicity of nicotine is well known and taken into account in the recommended posology. Nicotine was not mutagenic in appropriate assays. The results of carcinogenicity assays did not provide any clear evidence of a tumorigenic effect of nicotine. In studies in pregnant animals, nicotine showed maternal toxicity, and consequential mild fetal toxicity. Additional effects included pre- and postnatal growth retardation and delays and changes in postnatal CNS development.

Effects were only noted following exposure to nicotine at levels in excess of those which will result from recommended use of NiQuitin Lozenges. Effects on fertility have not been established.

Comparison of the systemic exposure necessary to elicit these adverse responses from preclinical test systems with that associated with the recommended use of NiQuitin Lozenges indicate that the potential risk is low and outweighed by the demonstrable benefit of nicotine therapy in smoking cessation. However, NiQuitin Lozenges should only be used by pregnant women on medical advice if other forms of treatment have failed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Mannitol
Sodium alginate
Xanthan gum
Potassium bicarbonate
Calcium polycarbophil
Sodium carbonate anhydrous
Aspartame
Magnesium stearate
Menthol mint flavour

6.2 Incompatibilities
None known.

6.3 Shelf life
Three years

6.4 Special precautions for storage
Do not store above 25°C. Store in the original package.
6.5 *Nature and contents of container*
Clear or opaque Polyvinyl Chloride/Polyethylene/Polyvinylidene Chloride blisters in packs of 12, 36, 72, 96, 108 and 144.
Not all pack sizes may be marketed.

6.6 *Special precautions for disposal*
None.

7 **MARKETING AUTHORISATION HOLDER**
Beecham Group plc
980 Great West Road
Brentford
Middlesex
TW8 9GS
United Kingdom
T/A GlaxoSmithKline Consumer Healthcare
Brentford TW8 9GS, UK.

8 **MARKETING AUTHORISATION NUMBER(S)**
PL 00079/0606

9 **DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**
29/03/2007

10 **DATE OF REVISION OF THE TEXT**
17/09/2007
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
NiQuitin 4 mg Lozenges

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each lozenge contains 4 mg nicotine (as 22.2 mg nicotine polacrilex). For excipients see Section 6.1.

3 PHARMACEUTICAL FORM
Lozenge
White, round lozenge with convex surfaces, debossed NL4 on one side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
NiQuitin Lozenges are indicated for the treatment of tobacco dependence by relief of nicotine withdrawal symptoms including cravings. Permanent cessation of tobacco use is the eventual objective. NiQuitin Lozenges can be used:

- for smoking cessation (abrupt and gradual).
- as an aid for smokers during temporary abstinence.

NiQuitin Lozenges should preferably be used in conjunction with a behavioral support programme.

4.2 Posology and method of administration

Directions for use:

NiQuitin 4 mg Lozenges are suitable for smokers who have their first cigarette of the day within 30 minutes of waking up.

One lozenge should be placed in the mouth and allowed to dissolve. Periodically, the lozenge should be moved from one side of the mouth to the other, and repeated, until the lozenge is completely dissolved (approximately 20 – 30 minutes). The lozenge should not be chewed or swallowed whole.

Users should not eat or drink while a lozenge is in the mouth.

Behavioural therapy, advice & support will normally improve the success rate.
**Adults (18 years and over):**

**Abrupt cessation of smoking:**

Users should make every effort to stop smoking completely during treatment with NiQuitin Lozenges.

Recommended treatment schedule:

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Step 2</th>
<th>Step 3 Weeks 10 to 12</th>
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<tbody>
<tr>
<td>Weeks 1 to 6</td>
<td>Weeks 7 to 9</td>
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During weeks 1 to 6 it is recommended that users take a minimum of 9 lozenges per day. Users should not exceed 15 lozenges per day.

To help stay smoke free beyond 12 weeks, users may take 1-2 lozenges per day only on occasions when they are strongly tempted to smoke.

Those who use the lozenges beyond 9 months are recommended to seek additional help and advice from a healthcare professional.

**Gradual cessation of smoking:**

For smokers who are unwilling or unable to quit abruptly.

Use a lozenge whenever there is a strong urge to smoke in order to reduce the number of cigarettes smoked as far as possible and to refrain from smoking as long as possible.

The number of lozenges a day is variable and depends on the patient's needs. Nonetheless it should not exceed 15 lozenges per day.

If a reduction in cigarette consumption has not been achieved after 6 weeks of treatment, a healthcare professional should be consulted.

Reduced tobacco consumption should lead to complete cessation of smoking. This should be attempted as soon as possible. When the number of cigarettes has been reduced to a level from which the user feels able to quit completely, then start on the schedule for “abrupt cessation” as given above.

If an attempt to stop smoking completely has not been started within 6 months after the beginning of treatment, it is recommended to consult a healthcare professional.

**Temporary abstinence:**

Use a lozenge every 1-2 hours to control troublesome withdrawal symptoms including cravings.

Users should not take more than 15 lozenges per day.

Users should be encouraged to stop smoking completely as soon as possible.
If users are still feeling the need to use lozenges on a regular basis 6 months after the start of treatment and have still been unable to undertake a permanent quit attempt, then it is recommended to seek additional help and advice from a healthcare professional.

**Adolescents and children:**
Adolescents (12-17 years) should follow the schedule of treatment for abrupt cessation of smoking as given above but, as data are limited, duration of NRT in this age group is restricted to 12 weeks. If longer treatment is required, or where adolescents are unwilling or unable to quit smoking abruptly, advice from a healthcare professional should be sought.

NiQuitin Lozenges are not recommended for use in children under 12 years of age.

### 4.3 Contraindications
NiQuitin Lozenges are contraindicated in:
- those with hypersensitivity to nicotine or any of the excipients;
- children under the age of 12 years and non-smokers.

### 4.4 Special warnings and precautions for use
The risks associated with the use of NRT are substantially outweighed in virtually all circumstances by the well established dangers of continued smoking.

*Patients hospitalised for MI, severe dysrhythmia or CVA who are considered to be haemodynamically unstable should be encouraged to stop smoking with non-pharmacological interventions.* If this fails, NiQuitin Lozenges may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision. Once patients are discharged from hospital they can use NRT as normal.

*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.

*Allergic reactions*: Susceptibility to angioedema and urticaria

A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions:

- **Renal and hepatic impairment**: Use 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.

- **Phaeochromocytoma and uncontrolled hyperthyroidism**: Use with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma as nicotine causes release of catecholamines.

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

*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.

*Stopping smoking*: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs catalysed by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops this may result in a slower metabolism and a consequent rise in blood levels of such drugs.

*Transferred dependence*: Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.
Phenylketonuria: NiQuitin Lozenges are sugar free, but do contain aspartame which metabolises to phenylalanine, which is of relevance for those with phenylketonuria.

Sodium content: Each NiQuitin Lozenge contains 15 mg of sodium. People on a low sodium diet should take this into account.

4.5 Interaction 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.

4.6 Pregnancy and lactation
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. 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.

However, as nicotine passes to the fetus affecting breathing movements and has a dose dependent effect on placental/fetal circulation, the decision to use NRT should be made as early on in the pregnancy as possible. The aim should be to use NRT for only 2-3 months.

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
Nicotine from smoking and NRT is found in breast milk. However the amount of nicotine the infant is exposed to from NRT 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
NRT can cause adverse reactions similar to those associated with nicotine administered in other ways, including smoking. These may be attributed to the pharmacological effects of nicotine, some of which are dose dependent. At recommended doses NiQuitin Lozenges have not been found to cause any serious adverse effects. Excessive consumption of NiQuitin Lozenges by those who have not been in the habit of inhaling tobacco smoke could possible lead to nausea, faintness or headaches.

Certain symptoms which have been reported such as depression, irritability, anxiety and insomnia may be related to withdrawal symptoms associated with smoking cessation. Subjects quitting
smoking by any means could expect to suffer from headache, dizziness, sleep disturbance, increased
coughing or a cold.

**Related adverse events with excess in active compared to placebo group in a controlled study.**

Platelet, bleeding and clotting disorders

Uncommon >1/1000; <1/100: gingival bleeding

Metabolic and nutritional disorders

Uncommon >1/1000; <1/100: thirst; excessive thirst

Psychiatric disorders

Common >1/100; <1/10: insomnia

Uncommon >1/1000; <1/100: anxiety; anxiety attack; anxiety reaction; nightmares;
marked restlessness; decreased appetite; lost appetite; lethargy

Central and peripheral nervous system disorders

Common >1/100; <1/10: dizziness; headache

Uncommon >1/1000; <1/100: migraine; mucosal burning; burning sensation; paraesthesia
mouth; sensory disturbance; hyperalertness

Respiratory system disorders

Common >1/100; <1/10: coughing; pharyngitis; sore throat

Uncommon >1/1000; <1/100: dyspnoea; shortness of breath; aggravated cough; lower
respiratory tract infection; respiratory disorder; excessive sneezing

Gastrointestinal system disorders

Very common >1/10: nausea; hiccup, flatulence

Common >1/100; <1/10: vomiting; constipation, diarrhea; dysphagia; dyspepsia;
heartburn; indigestion; belching; mouth irritation, mouth ulceration; tongue ulceration; dry
mouth; bloating

Uncommon >1/1000; <1/100: gastroesophageal reflux; oesophageal reflux aggravated;
retching; eructation; gagging; catarrh; increased saliva; lip ulceration; GI disorder;
abdominal griping; sore lips; dry throat

Special senses other, disorders:

Uncommon >1/1000; <1/100: taste perversion

Skin and appendages disorders:

Uncommon >1/1000; <1/100: itching; rash

Body as a whole: general disorders:

Uncommon >1/1000; <1/100: throat swelling; chest pain; tightness of chest; overdose
effect; withdrawal syndrome; malaise; hot flushes; halitosis
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 with oxygen should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: N07B A01

Nicotine is an agonist at nicotine receptors in the peripheral and central nervous system and has pronounced CNS and cardiovascular effects. When consumed in tobacco products, it has been shown to be addictive and abstinence is linked to craving and withdrawal symptoms. These craving and withdrawal symptoms include urge to smoke, depressed mood, insomnia, irritability, frustration or anger, anxiety, difficulty in concentrating, restlessness and increased appetite or weight gain. The lozenges replace some of the nicotine provided by tobacco and help reduce the severity of these nicotine craving and withdrawal symptoms.

5.2 Pharmacokinetic properties

NiQuitin Lozenges dissolve completely in the oral cavity, and the entire amount of nicotine contained in the lozenge becomes available for buccal absorption or ingestion (swallowing). The complete dissolution of NiQuitin Lozenges is typically achieved in 20-30 minutes. The peak plasma concentrations of nicotine achieved after single dose are approximately 10.8 ng/ml. When dosed every 1.5 hours, the steady state peak and trough concentrations are 26.0 and 19.7 ng/ml respectively. Ingestion of NiQuitin Lozenges not following dosing instruction (chewed, retained in the mouth, and swallowed; chewed and immediately swallowed) does not result in faster or higher absorption, but a substantial amount of nicotine (80-93%) is still absorbed.

As the plasma protein binding of nicotine is low (4.9% - 20%), the volume of distribution of nicotine is large (2.5 l/kg). The distribution of nicotine to tissue is pH dependent, with the highest concentrations of nicotine found in the brain, stomach, kidney and liver.

Nicotine is extensively metabolized to a number of metabolites, all of which are less active than the parent compound. The metabolism of nicotine primarily occurs in the liver, but also in the lung and kidney. Nicotine is metabolized primarily to cotinine but is also metabolized to nicotine N'-oxide. Cotinine has a half-life of 15-20 hours and its blood levels are 10 times higher than nicotine. Cotinine is further oxidized to \textit{trans}-3'-hydroxycotinine, which is the most abundant metabolite of nicotine in the urine. Both nicotine and cotinine undergo glucuronidation.

The elimination half-life of nicotine is approximately 2 hours (range 1 - 4 hours). Total clearance for nicotine ranges from approximately 62 to 89 l/hr. Non-renal clearance for nicotine is estimated to be about 75% of total clearance. Nicotine and its metabolites are excreted almost exclusively in the urine. The renal excretion of unchanged nicotine is highly dependent on urinary pH, with greater excretion occurring at acidic pH.

5.3 Preclinical safety data

The general toxicity of nicotine is well known and taken into account in the recommended posology. Nicotine was not mutagenic in appropriate assays. The results of carcinogenicity assays did not provide any clear evidence of a tumorigenic effect of nicotine. In studies in pregnant animals,
nicotine showed maternal toxicity, and consequential mild fetal toxicity. Additional effects included pre- and postnatal growth retardation and delays and changes in postnatal CNS development.

Effects were only noted following exposure to nicotine at levels in excess of those which will result from recommended use of NiQuitin Lozenges. Effects on fertility have not been established.

Comparison of the systemic exposure necessary to elicit these adverse responses from preclinical test systems with that associated with the recommended use of NiQuitin Lozenges indicate that the potential risk is low and outweighed by the demonstrable benefit of nicotine therapy in smoking cessation. However, NiQuitin Lozenges should only be used by pregnant women on medical advice if other forms of treatment have failed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Mannitol
Sodium alginate
Xanthan gum
Potassium bicarbonate
Calcium polycarbophil
Sodium carbonate anhydrous
Aspartame
Magnesium stearate
Menthol mint flavour

6.2 Incompatibilities
None known.

6.3 Shelf life
Three years

6.4 Special precautions for storage
Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container
Clear or opaque Polyvinyl Chloride/Polyethylene/Polyvinylidene Chloride blisters in packs of 12, 36, 72, 96, 108 and 144.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal
None.

7 MARKETING AUTHORISATION HOLDER
Beecham Group plc
8 MARKETING AUTHORISATION NUMBER(S)
PL 00079/0607

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
29/03/2007

10 DATE OF REVISION OF THE TEXT
17/09/2007
What are NiQuitin Lozenges and what are they used for?

Each lozenge contains 2 mg nicotine in the form of a mix of two compounds (nicotine polobutylester 11mg, Other ingredients are methylparaben, propylparaben, calcium carbonate, calcium phosphate, maltose, and sodium chloride). NiQuitin Lozenges are available in 36 and 72 lozenges per pack.

Who makes NiQuitin Lozenges?

The manufacturer of NiQuitin Lozenges is GlaxoSmithKline Consumer Healthcare, Brentford TW8 9BW, U.K. and all.

What are NiQuitin Lozenges for?

NiQuitin Lozenges are a stop smoking aid. They can help you stop smoking by helping you to cut down smoking before stopping completely. See more about how you should use NiQuitin Lozenges for further details.

NiQuitin Lozenges work by replacing some of the nicotine you are used to getting from smoking cigarettes. In the mouth in sugarfree that can make you feel addicted to them. This type of treatment is called Modified Release Therapy (MRT). NiQuitin Lozenges contain a nicotine wash and when asked, nicotine is released slowly from the main absorbed through the lining of the mouth. This also reduces some of the respiratory symptoms, such as a feeling for irritating, that smokers often feel when they try to give up or when they are in situations where they cannot have a cigarette. The nicotine can also reduce your cravings for a cigarette and helps you to resist the urge to smoke.

Because NiQuitin Lozenges do not contain the tar, cancer-causing substances, or other toxic substances in cigarettes, they do not have the health dangers of tobacco.

NiQuitin Lozenges come in two strengths, each strength comes in a range of packs. This pack contains NiQuitin 2 mg Lozenges. The recommended treatment course for smokers who have not tried to stop smoking before more than once or for smokers who have not tried to stop smoking before is to take 1 lozenge for at least 10 minutes after every cigarette you use. NiQuitin 2 mg Lozenges are available for people who usually have a threshold of 10 minutes of each of the satiety.

If possible, NiQuitin Lozenges should be used with a stop smoking to help you to stick to your programme – see the leaflet in this pack for more details. Behavioural therapy, advice, and support will normally improve your success rate.

Can you use NiQuitin Lozenges?

IMPORTANT

Do not use NiQuitin Lozenges if:

- you are allergic to nicotine or any other ingredients in the product
- you are pregnant or under the age of 12 years.

There are no health benefits to smoking. It is always better to give up smoking, and using MRT is not a substitute for these health benefits of continuing to smoke.

If you are pregnant, because a heart attack, severe heart disease, or stroke; you should tell your doctor if you are pregnant or plan to become pregnant. Your doctor will tell you if you should use MRT instead of patches.

How should you use NiQuitin Lozenges?

NiQuitin 2 mg Lozenges are suitable for smokers who have their first cigarette of the day more than 30 minutes after waking up.

They can be used for:

- Smoking cessation straightforward
- Quitting smoking step by step

See these sections below for further details.
UKPAR NiQuitin 2mg and 4mg Lozenges

If you think you can stop smoking straight away then you should however, if you feel this is too big a step then you may wish to cut down the amount of cigarettes you smoke as a first step before stopping completely.

How to use your lozenges
Put one lozenge in your mouth and periodically move it from side to side of your mouth to the other until it has completely dissolved. This should take 15 to 30 minutes.
- Do not chew the lozenge or swallow it whole.
- You should not or at first hate the lozenge in your mouth as this may reduce the absorption of the nicotine.
- Do not use more than 15 lozenges a day.
- If you feel you need to use the lozenges for longer than 9 months (36 weeks), then talk to a healthcare professional.

Adults (18 years and over)
Stopping smoking straight away is important that you make every effort to stop smoking completely. If you are trying to give up straight away. However, if you do smoke a cigarette while you are using NiQuitin, you should be aware that you should try to cut back on smoking and talk to a healthcare professional for help.

For the first week use at least 9 lozenges a day (maximum 15) and take one lozenge every 1 to 2 hours when you want an urge to smoke. You should then gradually reduce the number of times you use until you cannot or at first hate the lozenge in your mouth as this may reduce the absorption of the nicotine.

For the first 6 weeks use at least 3 lozenges a day (maximum 15) and take one lozenge every 3 to 4 hours during the day and at night to help you stop smoking. You can use 3 lozenges a day but only if you have taken no cigarettes for 48 hours. Once you are using 1 to 2 lozenges a day, you may occasionally feel a sudden craving to smoke, even after you have given up, and you can take a lozenge to help this.

Once you are using only 1 to 2 lozenges a day, try to stop using them altogether. However, you may occasionally feel a sudden craving to smoke, even after you have given up, and you can take a lozenge to help this.

Cutting down before stopping smoking
If stopping smoking straight away is too big a step for you, you can try cutting down the number of cigarettes you smoke first.

When you feel an urge to smoke, use a lozenge instead of a cigarette. Cut down the number of cigarettes you smoke each day as much as possible. If you have not been able to cut down the number of cigarettes you smoke each day after 6 weeks, talk to a healthcare professional.

As soon as you feel able, you should give up cigarettes completely. If you give up cigarettes completely, talk to the instructions for stopping smoking straight away and above. Do this as soon as possible. If you have not been able to make a quit attempt within 6 months of starting to use the lozenges, speak to a healthcare professional.

Teens aged 12 to 17 years old
You should follow the instructions above for stopping smoking straight away, but you should not use the lozenges for longer than 12 weeks. Use at least 9 lozenges a day (maximum 15) for the first 6 weeks then gradually reduce the number of times you use until you cannot or at first hate using the lozenges. If you think you may need to use the lozenges for longer than 12 weeks, or if you are not ready to stop smoking straight away, get advice from a healthcare professional.

Children under 12 years old should not use NiQuitin Lozenges.

Stop smoking is not always easy. If you are worried that you may start smoking again, or are finding it difficult to stop using NiQuitin, visit a healthcare professional for help. If you do start to smoke again, you can achieve your goal by getting the best results from further courses of NiQuitin.

What should you do if you take too many lozenges?
If you take too many NiQuitin Lozenges you may feel sick, dizzy and weak. Keep using the lozenges and get medical advice. Do not take any more lozenges until you talk to your doctor.

The lozenges are not suitable for children under 12 or non-smokers. They may develop signs of nicotine poisoning including headache, sickness, dizziness and fainting. If you think you have taken too many of the lozenges, contact your doctor or nearest hospital casualty department immediately. If possible, throw them in the packet or this leaflet.

Are there any side effects?
At the recommended doses NiQuitin Lozenges have not been found to cause any serious side effects. However, like any medicine, it can cause some symptoms such as dizziness, headache, sleep disturbance, cough and cold-like symptoms. Symptoms such as depression, irritability, anxiety and insomnia may also be related to withdrawal symptoms associated with giving up smoking.

Side effects of the nicotine in all NRT products are similar to those you might get from the nicotine in cigarette, and may include feeling sick, nausea, dizziness, tiredness, tiredness, dry mouth/throat, sweating, increase in appetite, increase in weight, nervousness, irritability, anxiety, tremor and increased heart rate. If these symptoms become worse, or persist, discontinue the use of the product. If any of the above side effects are usually serious, and often occur after a few days treatment, they may be troublesome and do not disappear, or if you experience any other unexpected effects, stop using the lozenges and tell a healthcare professional.

Where should I keep NiQuitin Lozenges?
Keep all medicines in a suitable container out of the reach and sight of children. Do not use the lozenges after the ‘Exp’ date shown on the pack.


If you have any questions or comments about NiQuitin Lozenges, please telephone our Information Line on 0800 100 122.

Glamorgan Consumer Healthcare Bradford
TFB 965012

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UKPAR NiQuitin 2mg and 4mg Lozenges

PL 00079/0606-7

Please read this leaflet before you start to use your lozenges and keep it until you have used them all as you may need to read it again. If you are unsure about anything, ask your doctor, nurse, pharmacist or other healthcare professional.

What are NiQuitin Lozenges and what are they used for?

Each Lozenge contains 2 mg nicotine in the form of a red and white complex (nicotine polacrilex 22.2 mg). Other ingredients are: sucrose, shellac, gelatin, maize starch, colloidal silicon dioxide (E551), magnesium stearate and blackcurrant.

When should you use NiQuitin Lozenges?

NiQuitin Lozenges are available in packs of 36 and 72 lozenges.

Who makes NiQuitin Lozenges?
The Marketing Authorisation Holder is GlaxoSmithKline Consumer Healthcare Limited, Sharpness, Tewkesbury, Gloucestershire, GL20 8BN. Any queries should be sent to this address.

What is the active ingredient in NiQuitin Lozenges?

The active ingredient is nicotine. Nicotine is the addictive substance which causes smoking addiction. People who use nicotine replacement products are helping to break their addiction to nicotine, which is the cause of their smoking habit.

What should you do if you take too much nicotine?

There is no specific antidote for nicotine poisoning. Its symptoms are similar to those of other poisons. It is important to seek medical advice in such cases.

How to store NiQuitin Lozenges?

The storage instructions given on the package leaflet are: Store below 25°C.

What to do if you get NiQuitin Lozenges in your eyes?

If you get NiQuitin Lozenges in your eyes, rinse them with plenty of water. NiQuitin Lozenges are not recommended for use in children.

What if you are pregnant or breast feeding?

NiQuitin Lozenges are not recommended for use in children.

How should you use NiQuitin Lozenges?

NiQuitin 4 mg Lozenges are suitable for smokers who have their first cigarette within 30 minutes of waking up.

Can you use NiQuitin Lozenges?

NiQuitin Lozenges are suitable for smokers who have their first cigarette within 30 minutes of waking up.
UKPAR NiQuitin 2mg and 4mg Lozenges  PL 00079/0606-7

If you think you can stop smoking straight away then you should. However, if you find this too big a step, then you may wish to try cutting down the amount of cigarettes you smoke as a first step before stopping completely.

How to use your lozenges

Put one lozenge in your mouth and periodically move it from side to side of your mouth to the other, until it has completely dissolved. This should take 15 to 20 minutes.

- Do not chew the lozenge or swallow it whole.
- You should not use more than one lozenge in your mouth at a time as this may reduce the absorption of the nicotine.
- Do not use more than 15 lozenges a day.

If you feel you need to use the lozenges for longer than 9 months (12 weeks for 32–42 year olds), you should talk to a healthcare professional.

Adults (18 years and over)

Stopping smoking straight away

It is important that you make every effort to stop smoking completely on your own. However, if you do smoke 8 cigarettes while you are using NRT, you should consider your next attempt to quit smoking and talk to a healthcare professional for help.

For the first 2 weeks use at least 9 lozenges a day (maximum 15) and take one lozenge every 1–2 hours when you have an urge to smoke. You should then gradually reduce the number of lozenges you use by taking one less lozenge every 2 days. Once you reach 3 lozenges a day, reduce the number of times you take the lozenge by 1 every 4 days. Once you reach 1 lozenge a day, reduce the frequency you take the lozenge every 6 days. You should aim to stop using the lozenge when you have an urge to smoke.

Once you are using only 1-2 lozenges a day, try using them altogether. However, you may occasionally feel a sudden craving to smoke, even a long time after you’ve given up, and you can take a lozenge if this happens.

Cutting down before stopping smoking

If stopping smoking straight away is too big a step for you, you can try cutting down the number of cigarettes you smoke first.

When you feel an urge to smoke, use a lozenge instead of a cigarette. Cut down the number of cigarettes you smoke each day by as many as possible. If you have not been able to cut down the number of cigarettes you smoke each day after 2 weeks, talk to a healthcare professional.

As soon as you feel able, you should give up cigarettes completely. Follow the instructions for stopping smoking straight away above. Do this as soon as possible. If you have not been able to make a quit attempt within 6 months of trying to use the lozenges, speak to a healthcare professional.

Young people aged 12 to 17 years old

You should follow the instructions above for stopping smoking straight away, but you should not use the lozenges for longer than 12 weeks. Use at least 9 lozenges a day (maximum 15) for the first 6 weeks then gradually reduce the number of lozenges you use before stopping completely. If you feel you need to use the lozenges for longer than 12 weeks, or if you are not ready to stop smoking straight away, get advice from a healthcare professional.

Do not exceed the stated dose.

Children under 12 years old should not use NiQuitin Lozenges.

If you are worried that you may start smoking again, or are finding it difficult to stop using NRT completely, talk to a healthcare professional. If you do start to smoke again, they can advise you on how to get the best results from further courses of NRT.

What should you do if you take too many lozenges?

If you take too many NiQuitin Lozenges you may start to feel sick, dizzy and irritable. Stop using the lozenges and get immediate medical advice from a doctor or hospital casualty department. If possible, throw the packet or this leaflet away.

The lozenges are not suitable for children under 12 or non-smokers. They may develop signs of nicotine overdose including headache, dizziness, stomach pain and diarrhoea. If you think you have eaten any of the lozenges, contact your doctor or nearest hospital casualty department immediately. If possible, show them this leaflet or this packet.

Are there any side effects?

At the recommended dose, NiQuitin Lozenges have not been found to cause any serious side effects.

Stopping smoking can cause some symptoms such as dizziness, nausea, a sore throat, mouth irritation, dryness around mouth, difficulty breathing, heartburn. Less common side effects include dryness, sweating, tight chest, shortness of breath, belching, increased need to ease, hoarseness, croakiness, bad breath, increases in saliva, stool frequency, constipation, dark patches on teeth, gums, tongue, mouth ulcers, mouth pain or discomfort, sore throat, swollen salivary glands, difficulty swallowing, dry mouth, heartburn, stomachache, tiredness.

None of the above side effects are usual, however, if you experience any other unusual effects, stop using the lozenges and talk to a healthcare professional.

When should I keep NiQuitin Lozenges?

Keep all lozenges in the carton, in their blister pack, until you are ready to use them. Do not store them above 25°C. Do not use the lozenges after the expiry date shown on the pack. Do not use NiQuitin to help you stop all medicines except for the mouth and nose. Take one lozenge every 1–2 hours when you have an urge to smoke.

If you have any questions or comments about NiQuitin Lozenges, please telephone our Information Line on 0500 100 222.

Classification

Glossopharyngeal pain is a registered trademark of the GlaxoSmithKline group of companies.