Public Assessment Report

Nicorette Fruit 2 mg and 4 mg Lozenge

(Nicotine resinate)

UK Licence No: PL 15513/0393-4

McNeil Products Limited
LAY SUMMARY

Nicorette Fruit 2 mg and 4 mg Lozenge
(Nicotine resinate)

This is a summary of the Public Assessment Report (PAR) for Nicorette Fruit 2 mg and 4 mg Lozenge (PL 15513/0393-4). For ease of reading, this medicinal product will be referred to as Nicorette Fruit Lozenge in this Lay Summary.

This summary explains how Nicorette Fruit Lozenge was assessed and its authorisation recommended, as well as the conditions of use. It is not intended to provide practical advice on how to use Nicorette Fruit Lozenge.

For practical information about using Nicorette Fruit Lozenge, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What is Nicorette Fruit Lozenge and what is it used for?
Nicorette Fruit Lozenge is a nicotine replacement therapy (NRT). It is used to relieve and/or prevent withdrawal symptoms and reduce the cravings when trying to stop smoking or when cutting down on the number of cigarettes smoked.

Nicorette Fruit Lozenge can also be used in pregnant or breastfeeding women to help them stop smoking, as the risks to the baby are far less than if they continue to smoke.

Nicorette Fruit Lozenge can be used to stop smoking completely by using it to replace all the cigarettes smoked. However, it can also be used in other ways:
- It can help cut down the number of cigarettes smoked
- When patients cannot or do not want to smoke. For example:
  - to avoid harm to others e.g. children or family
  - smoke free areas e.g. pub, work, public transport (e.g. aeroplanes).

Nicorette Fruit Lozenge may also help increase the motivation to quit. When making a quit attempt a behavioural support programme will increase the chances of success.

How does Nicorette Fruit Lozenge work?
Nicorette Fruit Lozenge contains the active ingredient nicotine resinate, which belongs to a group of medicines called nicotine replacement therapy (NRT). It acts to substitute the nicotine that patients normally get from cigarettes and can help them stop smoking.

How is Nicorette Fruit Lozenge used?
Nicorette Fruit Lozenge is taken orally. The lozenge must be placed in the mouth and allow it to slowly dissolve. This will release nicotine, which will absorb through the lining of the mouth. Nicorette Fruit Lozenge should NOT be chewed or swallowed.

The number of lozenges patients use each day will depend on how many cigarettes they smoked and how strong they were.

People who smoke 20 or less cigarettes a day should take the 2 mg nicotine lozenge to relieve cravings. The 4 mg lozenge should be used by people who smoke more than 20 cigarettes a day.

If people are able to stop smoking they should use the lozenge, when needed, in place of cigarettes. They should also reduce the number of lozenges used until they have stopped using them completely.
People who are unable to stop smoking or do not feel ready to quit at this time, they should replace as many cigarettes as possible with the lozenge. There are toxins in cigarettes that can cause harm to the body. Nicorette fruit lozenge provides a safer alternative to smoking, for smokers and those around them.

Reducing the amount of cigarettes may also help smokers to become more motivated to stop smoking. As soon as they are ready they should aim to stop smoking completely.

People can also use the lozenge on those occasions when they 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 behavioural therapy, advice and support will normally improve the success rate. People who have quit smoking and want to stop using Nicorette fruit lozenge but are finding this difficult should contact a doctor, nurse or pharmacist for advice.

**Adults and children aged 12 years and over**
The recommended dose in adults and children aged 12 years and over is one lozenge to be taken as required to relieve cravings.

Most people take between 8 to 12 lozenges per day. Patients must not take more than 15 lozenges per day and should not exceed the stated dose.

**Children under 12 years**
This medicine must not be given to children under 12 years.

Nicorette Fruit Lozenge is a general sale list (GSL) medicine.

Please read Section 3 of the PIL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

**What benefits of Nicorette Fruit Lozenge have been shown in studies?**
Nicorette Fruit Lozenge is line extension of Nicorette 2 mg and 4 mg Gum. As such the safety and efficacy data provided for Nicorette 2 mg and 4 mg Gum are accepted to be applicable for Nicorette Fruit Lozenges.

**What are the possible side effects from Nicorette Fruit Lozenge?**
The most common side effects with Nicorette Fruit Lozenge (which may affect more than 1 in 10 people) are headache, cough, feeling sick (nausea), throat irritation, hiccups and sore mouth or throat.

The common side effects with Nicorette Fruit Lozenge (which may affect up to 1 in 10 people) are allergic reactions (hypersensitivity), burning sensation in the mouth, dizziness, taste disturbance or loss of taste, tingling or numbness of the hands and feet, stomach pain or discomfort, diarrhoea, dry mouth, indigestion, excessive gas or wind, increased salivation, sore and inflamed mouth, tiredness (fatigue) and sickness (vomiting).

For the full list of all side effects reported with Nicorette Fruit Lozenge, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.
**Why is Nicorette Fruit Lozenge approved?**
The MHRA decided that Nicorette Fruit Lozenge’s benefits are greater than its risks and recommended that it be approved for use.

**What measures are being taken to ensure the safe and effective use of Nicorette Fruit Lozenge?**
A risk management plan has been developed to ensure that Nicorette Fruit Lozenge is used as safely as possible. Based on this plan, safety information has been included in the Summaries of Product Characteristics (SmPC) and the PIL for Nicorette Fruit Lozenge, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients and healthcare professionals will be monitored and reviewed continuously as well.

**Other information about Nicorette Fruit Lozenge**
Marketing Authorisations for Nicorette Fruit Lozenge was granted in the UK on 04 May 2018.

The full PAR for Nicorette Fruit Lozenge follows this summary.

This summary was last updated in July 2018.
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I Introduction

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) granted McNeil Products Limited Marketing Authorisations for the medicinal products Nicorette Fruit 2 mg and 4 mg Lozenge (PL 15513/0393-4) on 04 May 2018.

Nicorette Fruit 2 mg and 4 mg Lozenge is available as a general sales list (GSL). This product 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.

This product is also indicated in pregnant and lactating women making a quit attempt.

These applications were submitted in accordance with Article 8(3) of Directive 2001/83/EC, as amended, for a known active substance. These are line extensions of Nicorette 2 mg and 4 mg Gum, which were originally granted to Pharmacia Laboratories Limited (PL 00022/0101-2) on 14 May 1992. Following change of ownership the Marketing Authorisations were transferred to Pharmacia Limited (PL 00032/0248-9) on 26 April 1999, and then to the current Marketing Authorisation Holder, Mcneil Products Limited (PL 15513/0169-70), on 18 January 2008. These products are similar to the currently marketed Nicorette cools 2 mg and 4 mg Lozenge (PL 15513/0374-5) with the exception of flavouring.

Nicotine is an agonist at nicotine receptors in the peripheral and central nervous system and has pronounced central nervous system (CNS) and cardiovascular effects. Abrupt cessation of the use of tobacco-containing products following a prolonged period of daily use results in a characteristic withdrawal syndrome that includes four or more of the following: dysphoria or depressed mood; insomnia; irritability, frustration or anger; anxiety; difficulty concentrating, restlessness or impatience; decreased heart rate; and increased appetite or weight gain. Nicotine craving is an important element in the withdrawal syndrome after smoking cessation.

No new non-clinical or clinical studies were conducted for these products. However, in support of these applications the applicant has provided a comparison of the compositions of Nicotine Fruit Lozenge and Nicorette Strong Mint Lozenge.

A summary of the pharmacovigilance system and a detailed Risk Management Plan (RMP) have been provided with these applications, and these are satisfactory.

No new or unexpected safety concerns arose during the review of information provided by the Marketing Authorisation Holder and it was, therefore, judged that the benefits of taking Nicorette Fruit 2 mg and 4 mg Lozenge outweigh the risks and Marketing Authorisations were granted.
II Quality Aspects

II.1 Introduction

The finished product is a lozenge. Each lozenge contains 2 mg or 4 mg nicotine (as nicotine resinate), as active ingredient. The excipients present are mannitol (E421), xanthan gum (E415), tutti frutti flavour spray dried (contains orange oil, orange oil terpenes, isoamyl butyrate, citral, and gum acacia), sodium carbonate anhydrous (E500) (i), sucralose (E955), acesulfame potassium (E950) and magnesium stearate (E470b) making up the core. The coating is composed of hypromellose (E464), tutti frutti flavour liquid (contains orange oil, orange oil terpenes, isoamyl butyrate and citral), titanium dioxide (E171), sucralose (E955), acesulfame potassium (E950), polysorbate 80 and sepi film gloss (contains hypromellose (E464), mica-based pearlescent pigments).

All excipients comply with their respective European Pharmacopoeia monographs with the exception of Tutti frutti flavour spray dried and tutti frutti flavour liquid which comply with in-house specifications. Satisfactory Certificates of Analysis have been provided for all excipients showing compliance with their proposed specifications.

This product does not contain or consist of genetically modified organisms (GMO).

The finished product is packaged in polypropylene container with silica gel desiccant (“Flip pack”) with pack sizes of 20 (1x20) and 80 (4x20) lozenges. Not all pack sizes may be marketed.

Satisfactory specifications and Certificates of Analysis have been provided for all packaging components.

II.2 Drug Substance

INN: Nicotine resinate

Chemical Name: 2-methyl-2-propenoic acid, polymer with diethenylbenzene, compd. with (S)-3- (1-methyl-2-pyrrolidinyl)pyridine

Structure:

![Chemical Structure](image)

Molecular formula: \( C_{10}H_{14}N_2 ((C_{10}H_{10})_y(C_4H_6O_2)_x)_z \)

Molecular weight: 162.2 g/mol

Appearance: Off-white fine powder

Solubility: Nicotine resinate is practically insoluble in water

Nicotine resinate is the subject of a European Pharmacopoeia monograph.

All aspects of the manufacture and control of the active substance, nicotine resinate, are covered by a European Directorate for the Quality of Medicines and Healthcare (EDQM) Certificate of Suitability.

II.3 Medicinal Product

Pharmaceutical Development

The aim of the pharmaceutical development programme was to produce a fruit flavoured nicotine lozenge that will meet the needs of more smokers during quit attempts. The formulation strategy for
Nicotine Fruit 2 mg and 4 mg Lozenge (NFL) was to utilize the experience and results from the development work of Nicotine Strongmint 2 mg and 4 mg Lozenge (NSL).

Comparative in vitro dissolution profiles have been provided for NFL and NSL.

**Manufacture of the product**
Satisfactory batch formulae have been provided for the manufacture of the products, along with an appropriate account of the manufacturing process. A validation report for pilot scale batches has been provided. The process validation data provided is satisfactory. The applicant has stated that process validation will be performed on full scale batches.

**Finished Product Specifications**
The proposed finished product specifications are acceptable. The test methods have been described and have been adequately validated. Batch data have been provided that comply with the release specification. Certificates of Analysis have been provided for all working standards used.

**Stability of the Products**
Finished product stability studies were performed in accordance with current guidelines on batches of finished product in the packaging proposed for marketing. The data from these studies support a shelf-life of 36 months with no special storage conditions.

Suitable post approval stability commitments have been provided to continue stability testing on batches of finished product.

**II.4 Discussion on chemical, pharmaceutical and biological aspects**
There are no objections to the approval of these applications from a pharmaceutical viewpoint.

**III Non-Clinical Aspects**

**III.1 Introduction**
These applications are line extensions of already approved products. Therefore, the non-clinical assessment was limited to a discussion of the safety of the degradants of nicotine in the drug product and the impurities in nicotine as well as excipients in Nicotine Fruit Lozenge 2 and 4 mg Lozenge.

As the pharmacodynamic, pharmacokinetic and toxicological properties of nicotine resinate are well-known, no new non-clinical studies are required, and none have been provided. An overview based on the literature review is, thus, appropriate.

The Applicant’s non-clinical expert report has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the relevant non-clinical pharmacology, pharmacokinetics and toxicology.

**III.2 Pharmacology**
Not applicable for this product type. Refer to section ‘III.1; Introduction’ detailed above.

**III.3 Pharmacokinetics**
Not applicable for this product type. Refer to section ‘III.1; Introduction’ detailed above.

**III.4 Toxicology**
Not applicable for this product type. Refer to section ‘III.1; Introduction’ detailed above.
III.5 Ecotoxicity/environmental risk assessment (ERA)
Nicorette Fruit 2 mg and 4 mg Lozenge is the same as a mint flavoured product, already widely marketed in Europe, with the only difference of fruit flavouring; hence the expectation is that environmental exposure to nicotine will not increase due to the approval of the fruit flavoured product, as it is targeting the same patient population that is already being served with use of the mint flavoured product.

The sole active pharmaceutical ingredient (API) is nicotine (delivered as nicotine resinate), some of which, after it is administered, can enter into wastewater. Nicotine is expected to remain predominantly in the aqueous phase after emission into the sewage system, after which it is expected to undergo complete biodegradation to elements found in nature. Chronic toxicity tests have been conducted with aquatic organisms from three trophic levels and respiration inhibition has been tested for activated sludge microorganisms.

The results of Phase I and Phase II assessments indicated a predicted effect concentration (PEC)/predicted no-effect concentration (PNEC) value less than the threshold of concern identified in the Guideline. As a result, no precautionary and safety measures (e.g., labelling) are currently proposed.

III.6 Discussion on the non-clinical aspects
There is a well-established toxicity profile for nicotine and documented safety profile for the degradants, impurities, solvent and excipients and that all components of Nicotine Fruit 2 mg and 4 mg Lozenge have been qualified.

There are no objections to the approval of these applications from a non-clinical viewpoint.

IV Clinical Aspects
IV.1 Introduction
The applicant is introducing a product which is identical to the currently marketed Nicorette cools 2 mg and 4 mg Lozenge with only important difference in excipients pertinent to change in flavour.

The clinical pharmacology of nicotine is well-known. No new pharmacodynamics or pharmacokinetic data are provided or are required for these applications. No new efficacy or safety studies have been performed and none are required for this type of applications.

A comprehensive review of the published literature has been provided by the applicant, citing the well-established clinical pharmacology, efficacy and safety of nicotine.

IV.2 Pharmacokinetics
In support of these applications, the applicant has provided comparison of the compositions of Nicotine Fruit Lozenge and Nicorette Strong Mint Lozenge.

The minor difference in excipients is unlikely to result in any change in pharmacokinetics (PK) of the products. Since these applications are also line extensions a bioequivalence study is not deemed necessary.
IV.3 Pharmacodynamics
No new pharmacodynamic data has been submitted with these line extension applications and no new pharmacodynamics related claims have been made.

IV.4 Clinical efficacy
No new efficacy data have been submitted with these line extension applications and no new claims regarding efficacy have been made.

IV.5 Clinical safety
No new safety data have been submitted with these line extension applications and no claims regarding safety have been made.

IV.6 Risk Management Plan (RMP) and Pharmacovigilance system
The Marketing Authorisation Holder (MAH) has submitted an RMP, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to Nicorette Fruit 2 and 4 mg Lozenge.

A summary of safety concerns, as approved in the RMP, is listed below:

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<tr>
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</tr>
<tr>
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<td>None</td>
</tr>
</tbody>
</table>

Routine pharmacovigilance and routine risk minimisation are proposed for all safety concerns.

IV.7 Discussion on the clinical aspects
The grant of Marketing Authorisations is recommended for these applications, from a clinical point of view.

V User consultation
User testing of the package leaflet has been accepted, based on bridging reports provided by the applicant making reference to the user-testing of the PIL for Nicorette Cools 2 mg and 4 mg Lozenge (PL 15513/0374-0375). The products are from the same therapeutic class and have similar indications. A critical analysis demonstrated that the key messages for safe and effective use for both leaflets were similar. The justification on the rationale for bridging is accepted.

VI Overall conclusion, benefit/risk assessment and recommendation
The quality of the products is acceptable, and no new non-clinical or clinical concerns have been identified. Extensive clinical experience with nicotine resinate is considered to have demonstrated the therapeutic value of the active substance. The products are line extension of the existing authorised products. The benefit/risk is, therefore, considered to be positive.
Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and Labels

In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPC) and Patient Information Leaflets (PIL) for products granted Marketing Authorisations at a national level are available on the MHRA website.

The approved labelling for Nicorette Fruit 2 mg and 4 mg Lozenge is presented below:
Nicorette Fruit 2 mg and 4 mg Lozenge

Use: This product is suitable for those smoking 20 or less cigarettes a day. Nicorette Fruit 2 mg lozenge is used to replace smoking or prevent withdrawal symptoms and reduce the craving you get when you try to stop smoking or when cutting down the number of cigarettes you smoke. It provides a slower delivery of nicotine compared to other nicotine replacement products, such as gum and patches.

Nicorette Fruit 2 mg lozenge is not a medicine. It is a nicotine replacement product. Nicorette Fruit 2 mg lozenge is not for use during pregnancy.

Nicorette Fruit 2 mg lozenge is not a medicine. It is a nicotine replacement product. Nicorette Fruit 2 mg lozenge is not for use during pregnancy.

The active ingredient, nicotine, is the drug that makes the fruit-flavored lozenge work. Nicotine is also the drug in tobacco that makes it hard to stop smoking.

Nicorette Fruit 2 mg lozenge may help you stop smoking or cut down the number of cigarettes you smoke. Nicorette Fruit 2 mg lozenge contains 2 mg nicotine per lozenge.

Nicorette Fruit 2 mg lozenge is not a medicine. It is a nicotine replacement product. Nicorette Fruit 2 mg lozenge is not for use during pregnancy.

For adults and children aged 12 years and over.

Nicorette Fruit 2 mg lozenge comes with a piperazine tablet, which dissolves in the mouth. Do not swallow the tablet. Place the lozenge in your mouth and allow to dissolve. Use 1 lozenge when you usually take 12 cigarettes per day. Do not use more than 55 lozenges per day. Read the information leaflet carefully before use.

1 lozenge contains 2 mg nicotine. Each lozenge contains 7 mg aspartame (E951). Nicorette Fruit 2 mg lozenge is not for use during pregnancy.

Nicorette Fruit 2 mg lozenge comes with a piperazine tablet, which dissolves in the mouth. Do not swallow the tablet. Place the lozenge in your mouth and allow to dissolve. Use 1 lozenge when you usually take 12 cigarettes per day. Do not use more than 55 lozenges per day. Read the information leaflet carefully before use.

Nicorette Fruit 2 mg lozenge contains 2 mg nicotine. Each lozenge contains 7 mg aspartame (E951). Nicorette Fruit 2 mg lozenge is not for use during pregnancy.

Nicorette Fruit 2 mg lozenge comes with a piperazine tablet, which dissolves in the mouth. Do not swallow the tablet. Place the lozenge in your mouth and allow to dissolve. Use 1 lozenge when you usually take 12 cigarettes per day. Do not use more than 55 lozenges per day. Read the information leaflet carefully before use.

Nicorette Fruit 2 mg lozenge contains 2 mg nicotine. Each lozenge contains 7 mg aspartame (E951). Nicorette Fruit 2 mg lozenge is not for use during pregnancy.
PAR Nicorette Fruit 2 mg and 4 mg Lozenge

nicorette
fruit - 2 mg lozenge - nicotine

User: This product strength is suitable for those smoking 20 or less cigarettes a day. NICORETTE® Fruit 2 mg lozenges are used to help you stop smoking in a number of ways. Do not use more than 10 lozenges per day. Do not use if you are allergic to any of the ingredients listed below. You are more likely to quit smoking when using this product with help from your pharmacist, doctor, a trained counselor or a support program.

Cautions: This pack contains 60 (1 x 50) compressed lozenges, each containing 2 mg nicotine. Other ingredients are mannitol (E421), saccharin (E425), saccharin sodium (E425), sucrose (E341), dextrose (E341), high-activity gum arabic (E414), sodium saccharin (E953), magnesium stearate (E460), lactose (E907), sodium aluminium phosphate (E546), microcrystalline cellulose (E460), sorbitol, glycerol. Storage: Keep out of the reach of children. Dispose of sensitivity. Please read the enclosed leaflet for instructions.

Batch No: 770438

39578651581231

Use before:

McNeill Products Ltd
Maidenhead, Berkshire, SL6 9DG, UK

PL 15513/0393-4
Nicorette Fruit 2 mg and 4 mg Lozenge

nicorette
fruit · 4 mg lozenge
nicotine

4 x 20 lozenges

for those who smoke more than 20 a day

for those who smoke more than 20 a day
BRAILLE N430

nicorette®

fruit 4mg lozenge - nicotine

Use: This product strength is suitable for those smoking more than 20 cigarettes a day. NICORETTE® fruit 4mg lozenges are used to help you quit smoking and reduce the cravings you get when you try to stop smoking or when cutting down the number of cigarettes you smoke. It provides a safe alternative to smoking for both the individual and those around them.

Ideally you should aim to stop smoking. However, NICORETTE® fruit 4mg lozenges can be used in a number of ways, either to completely replace all your cigarettes, or if you do not feel ready to stop smoking completely, to replace certain cigarettes and therefore help you cut down the number of cigarettes you smoke. It may also help increase your motivation to quit.

Directions: For adults and children aged 12 years and over, do not chew or swallow the lozenges. Place the lozenge in your mouth and allow to dissolve. Use 1 lozenge/7 when required, usually 6-12 lozenges per day. Do not use more than 55 lozenges per day. Read the information leaflet carefully before use.

Warning: Do not take more medicine than the label tells you to.

If you are pregnant, talk to your doctor, pharmacist or nurse before using this product. If you need any advice before starting to use this product, talk to your doctor, pharmacist or nurse.

Do not use if you are allergic to any of the ingredients listed below.

Contents: The pack contains 80 (4 x 20) compressed lozenges, each containing 4mg nicotine (as nicotine resinate). Other ingredients are mannitol (E421), vanillin gum (E415), sucrose (E950), ascorbic acid potassium (E905), magnesium stearate (E475), titanium dioxide (E171), xanthan gum, sodium carbonate anhydrous (E500), hydroxypropyl cellulose (E464), magnesium stearate, sodium carbonate anhydrous (E500), tartaric acid, sodium bicarbonate (E500), sodium chloride (E508), polyethylene glycol 80. See leaflet for further information.

Storage: Keep out of the sight and reach of children.

Para-parally, please read the enclosed leaflet for instructions.
Use: This product strength is suitable for those smoking more than 20 cigarettes a day. NICORETTE® fruit 2mg lozenge is used to relieve and/or prevent withdrawal symptoms and reduce the cravings you get when you try to stop smoking or when cutting down the number of cigarettes you smoke. It provides a safer alternative to smoking for both the individual and those around them.

Ideally you should aim to stop smoking. However, NICORETTE® fruit 4mg lozenge can be used in a number of ways, either to completely replace all your cigarettes, or if you do not feel ready to stop smoking completely, to replace certain cigarettes and therefore help you cut down the number of cigarettes you smoke. It may also help increase your motivation to quit.

Directions: For adults and children aged 12 years and over. Do not chew or swallow the lozenge. Place the lozenge in your mouth and allow to dissolve. Use 1 lozenge when required, usually 8-12 lozenges per day. Do not use more than 15 lozenges per day. Read the information leaflet carefully before use.

Warning: Do not take more medicine than the label tells you to.

If you are pregnant, talk to your doctor, pharmacist or nurse before using this product. If you need any advice before starting to use this product, talk to your doctor, pharmacist or nurse.

Do not use if you are allergic to any of the ingredients listed below.

You are more likely to quit smoking when using this product with help from your pharmacist, doctor, a trained counsellor or a support programme.

Contents: The pack contains 80 (4 x 20) compressed lozenges, each containing 4mg nicotine (as nicotine resinate). Other ingredients are mannitol (E421), xanthan gum (E415), sucralose (E955), acesulfame potassium (E950), magnesium stearate (E470b), titanium dioxide (E171), tutti frutti flavour, sodium carbonate anhydrous (E500) (i), hypromellose (E464), microcrystalline cellulose (E460), sepiolite, polysorbate 80. See leaflet for further information.

Storage: Keep out of the sight and reach of children. Dispose of sensibly. Please read the enclosed leaflet for instructions.
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