# Nicotine 1 mg Compressed Lozenge
# Nicotine 2 mg Compressed Lozenge

**PL 00030/0463-0468**

**UKPAR**

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LAY SUMMARY

Nicotine 1 mg Compressed Lozenge
Nicotine 2 mg Compressed Lozenge

This is a summary of the Public Assessment Report (PAR) for Nicotine 1 mg Compressed Lozenge (PL 00030/0463, 0465, and 0467) and Nicotine 2 mg Compressed Lozenge (PL 00030/0464, 0466 and 0468). It explains how the applications for Nicotine 1 mg and 2 mg Compressed Lozenge were assessed and their authorisation recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use Nicotine 1 mg and 2 mg Compressed Lozenge.

For practical information about using Nicotine 1 mg and 2 mg Compressed Lozenge, patients should read the package leaflet or contact their doctor or pharmacist.

The products may be referred to as Nicotine 1 mg and 2 mg Lozenge in this report.

What are Nicotine 1 mg and 2 mg Lozenge and what are they used for?

These medicines are the same as Boots NicAssist 1 mg (PL 00030/0209) and 2 mg Compressed Lozenge (PL 00030/0203), which are already authorised in the UK. The licence holder (Novartis Consumer Health (UK) Limited) for Boots NicAssist 1 mg (PL 00030/0209) and 2 mg Compressed Lozenge (PL 00030/0203) has agreed that its scientific data can be used as a basis for the grant of identical licences for Nicotine 1 mg and 2 mg Compressed Lozenges (informed consent).

Nicotine 1 mg and 2 mg Compressed Lozenge are used to relieve the nicotine withdrawal symptoms in nicotine dependency, as an aid to smoking cessation.

Patient counselling and support normally improve the success rate.

How do Nicotine 1 mg and 2 mg Lozenge work?

Nicotine 1 mg and 2 mg Lozenge contain nicotine, which is one of the substances contained in tobacco. These medicinal products belong to a group of medicines which are used to help patients stop smoking. When sucked, nicotine is released slowly and absorbed through the lining of the mouth.

How are Nicotine 1 mg and 2 mg Lozenge used?

Nicotine 1 mg and 2 mg Lozenge are available as compressed lozenges in 1 mg and 2 mg strengths and are taken by mouth. The lozenges should be held in the mouth and allowed to dissolve. The lozenges should not be swallowed.

Nicotine 1 mg and 2 mg Lozenges should always be taken exactly as stated in this package leaflet. The patient should check with his/her doctor or pharmacist if he/she is not sure.

The appropriate dose will depend on the patient’s previous smoking habits.

Nicotine 1 mg Lozenge is recommended in low to moderate nicotine dependent smokers. Nicotine 1 mg Lozenge is not recommended for smokers with a strong or very strong nicotine dependency.

Nicotine 2 mg Lozenge is recommended if:
- The patient is a smoker with a strong or very strong nicotine dependency.
- The patient has previously failed to stop smoking with the 1 mg lozenge.
- The patient’s withdrawal symptoms remain so strong as to threaten relapse.
Otherwise 1 mg Nicotine Lozenge should be used.
Instruction for use:
1. Suck a lozenge until the taste becomes strong.
2. Allow the lozenge to rest between the gum and cheek.
3. Suck again when the taste has faded.
4. Repeat this routine until the lozenge dissolves completely (about 30 minutes).

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

Nicotine 1 mg and 2 mg Lozenge can be obtained without a prescription, at pharmacies, supermarkets and other retail outlets without the supervision of a pharmacist.

What benefits of Nicotine 1 mg and 32 mg Lozenge have been shown in studies?
The applications for Nicotine 1 mg and 2 mg Lozenge (PL 0463-0468) are considered to be identical to the previously authorised licences for Boots NicAssist 1 mg (PL 00030/0209) and 2 mg Compressed Lozenge (PL 00030/0203), respectively, with the same benefits and risks. So, no new studies have been provided for Nicotine 1 mg and 2 mg Lozenge. However, reference is made to the studies for Boots NicAssist 1 mg (PL 00030/0209) and 2 mg Compressed Lozenge (PL 00030/0203), respectively.

What are the possible side effects from Nicotine 1 mg and 2 mg Lozenge?
Like all medicines, Nicotine 1 mg and 2 mg Lozenge can cause side effects, although not everybody gets them. Some effects the patient may notice in the first few days are dizziness, headache and sleep disturbances. These may be withdrawal symptoms in connection with smoking cessation and may be caused by insufficient administration of nicotine.

Common side effects (affects 1 to 10 users in 100)
• dizziness and headache.
• dryness of the mouth, hiccups, stomach trouble such as nausea, flatulence, heartburn, increased saliva production and irritation of the mouth and throat may also occur, especially as a result of intense sucking. Slower sucking will usually overcome this problem.

For the full list of all side effects reported with Nicotine 1 mg and 2 mg Lozenge, see section 4 of the package leaflets.

For the full list of restrictions, see the package leaflets.

Why are Nicotine 1 mg and 2 mg Lozenge approved?
No new or unexpected safety concerns arose from these applications. The MHRA, therefore, considered that the benefits of Nicotine 1 mg and 2 mg Lozenge outweigh their risks; and the grant of Marketing Authorisations was recommended.

What measures are being taken to ensure the safe and effective use of Nicotine 1mg and 2 mg Lozenge?
A Risk Management Plan has been developed to ensure that Nicotine 1 mg and 2 mg Lozenge are used as safely as possible. Based on this plan, safety information has been included in the Summaries of Product Characteristics and the package leaflet for Nicotine 1 mg and 2 mg 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/healthcare professionals will be monitored/reviewed continuously.
Other information about Nicotine 1 mg and 2mg Lozenge.
Marketing Authorisations were granted in the UK on 15 January 2015.

The full PAR for Nicotine 1 mg and 2 mg Lozenge follows this summary.

For more information about treatment with Nicotine 1 mg and 2 mg Lozenge, read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in March 2015.
SCIENTIFIC DISCUSSION

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INTRODUCTION

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Novartis Consumer Health (UK) Limited Marketing Authorisations for the medicinal products Nicotine 1 mg Lozenge (PL 00030/0463, 0465, and 0467) and Nicotine 2 mg Lozenge (PL 00030/0464, 0466 and 0468) on 15 January 2015. The products are General Sales Licence (GSL) medicines indicated for the relief of nicotine withdrawal symptoms, in nicotine dependency as an aid to smoking cessation.

Patient counselling and support normally improve the success rate.

The applications were submitted as abridged applications according to Article 10c of Directive 2001/83/EC, as amended, cross-referring to Boots NicAssist 1 mg (PL 00030/0209) and 2 mg Compressed Lozenge (PL 00030/0203), respectively. Boots NicAssist 1 mg (PL 00030/0209) and 2 mg Compressed Lozenge (PL 00030/0203) were granted Marketing Authorisations in the UK to Novartis Consumer Health (UK) Limited on 01 August 2003 and 09 April 2003, respectively, following an Incoming Mutual Recognition procedure wherein Sweden was the Reference Member State and the UK was a Concerned Member State.

Nicotine 1 mg and Lozenge contain the active ingredient nicotine (as nicotine bitartrate dihydrate). Nicotine belongs to the pharmacotherapeutic group ‘Drugs used in nicotine dependence (N07B A01) and is a nicotine receptor agonist in the peripheral and central nervous systems; it has pronounced CNS and cardiovascular effects.

No new data were submitted nor were necessary to be submitted for these applications, as the data are identical to those of the previously granted cross-reference products.
1. INTRODUCTION
These are abridged applications for Nicotine 1 mg Lozenge (PL 00030/0463, 0465, and 0467) and Nicotine 2 mg Lozenge (PL00030/0464, 0466 and 0468) submitted under Article 10c of Directive 2001/83/EC, as amended.

The applications cross-refer to Boots NicAssist 1 mg (PL 00030/0209) and 2 mg Compressed Lozenge (PL 00030/0203), respectively, which were granted Marketing Authorisations in the UK to Novartis Consumer Health (UK) Limited on 01 August 2003 and 09 April 2003, respectively. The applications are considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM
2.1. Name
The proposed names of the products are Nicotine 1 mg and 2 mg Compressed Lozenge. The products have been named in line with current requirements.

2.2. Strength, pharmaceutical form, route of administration, container and pack sizes
Each compressed lozenge contains 1 mg or 2 mg of nicotine (corresponding to 3.072 mg or 6.144 mg nicotine bitartrate dihydrate respectively).

The products are packaged in opaque blisters consisting of aluminium foil and polyvinylchloride/polyethylene/polyvinylidene chloride/polyethylene/polyvinylchloride (PVC/PE/PVDC/PE/PVC) film, in pack sizes of 12, 36, 72, 96, 144 and 204 compressed lozenges.

Not all pack sizes may be marketed.

The proposed shelf life for the products is 3 years, with the special storage conditions ‘Do not store above 25°C’. The packaging, proposed shelf-life and storage conditions are consistent with the details registered for the respective cross-reference products.

2.3. Legal status
On approval, the products will be available as General Sales Licence (GSL) medicines.

2.4. Marketing Authorisation Holder/Contact Persons/Company
Novartis Consumer Health (UK) Limited, Park View, Riverside Way, Watchmoor Park, Camberley, Surrey, GU15 3YL, United Kingdom
The Qualified Person (QP) responsible for pharmacovigilance is stated and a satisfactory CV has been provided.

2.5 Manufacturers
The proposed manufacturing sites are consistent with those registered for the cross-reference products and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

2.6. Qualitative and quantitative composition
The proposed compositions are consistent with the details registered for the cross-reference products.

2.7. Manufacturing process
The proposed manufacturing process is consistent with the details registered for the respective cross-reference products and the maximum batch sizes are stated.

2.8. Finished product/shelf-life specification
The proposed finished product specifications are consistent with the details registered for the respective 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
None of the excipients contain materials of animal or human origin. This is consistent with the cross-reference products.

2.11. Bioequivalence
No bioequivalence data are required to support these simple abridged applications because the proposed products are manufactured to the same formula and utilise the same processes as the reference products Boots NicAssist 1 mg and 2 mg Compressed Lozenge (PL 00030/0209 and PL 00030/0203; Novartis Consumer Health (UK) Limited).

3. EXPERT REPORT
The applicant cross-refers to the data for Boots NicAssist 1 mg and 2 mg Compressed Lozenge (PL 00030/0209 and PL 00030/0203; Novartis Consumer Health (UK) Limited) to which these applications are claimed to be identical. This is acceptable.

4. PRODUCT NAME & APPEARANCE
See Section 2.1 for details of the proposed product names. The appearance of each product is identical to the respective cross-reference products.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPCs)
The proposed SmPCs are consistent with the details registered for the cross-reference products.

6. PATIENT INFORMATION LEAFLET (PIL) AND LABELLING
PIL
The PIL has been prepared in line with the details registered for the cross-reference products.
Carton and label
The proposed text is consistent with that for the cross-reference products. The Marketing Authorisation holder has committed to submitting mock-ups to the relevant regulatory authorities for approval before marketing any pack size.

7. CONCLUSION
The data submitted with the applications are acceptable. The grant of Marketing Authorisations is recommended.
NON-CLINICAL ASSESSMENT

As these are abridged applications submitted under Article 10c of Directive 2001/83/EC, as amended, no new non-clinical data have been supplied and none are required.

Suitable justification has been provided for non-submission of an Environmental Risk Assessment. As the applications are identical versions of already authorised products, it is not expected that environmental exposure will increase following approval of the Marketing Authorisations for the proposed products.

The grant of Marketing Authorisations is recommended.
CLINICAL ASSESSMENT

As these are abridged applications submitted under Article 10c of Directive 2001/83/EC, as amended, no new clinical data have been supplied and none are required.

The Marketing Authorisation Holder has provided details of a suitable pharmacovigilance system that fulfils the requirements and provides adequate evidence that they have the services of a qualified person responsible for pharmacovigilance, and have the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

An acceptable Risk Management Plan (RMP) has been submitted. Routine risk minimisation is provided through the Summary of Product Characteristics and the Patient Information Leaflet and this is sufficient.

The grant of Marketing Authorisations is recommended.
OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

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

NON-CLINICAL
No new non-clinical data were submitted and none are required for applications of this type.

EFFICACY
These applications are identical to the previously granted licences for Boots NicAssist 1 mg and 2 mg Compressed Lozenge (PL 00030/0209 and PL 00030/0203; Novartis Consumer Health (UK) Limited).

SAFETY
No new safety data were supplied or required for these applications. Nicotine has a well-established safety profile. No new or unexpected safety concerns arose from these applications.

PRODUCT LITERATURE
The SmPCs and PILs text are satisfactory, and consistent with those for the cross-reference products. The labelling text complies with statutory requirements and is satisfactory.

BENEFIT/RISK ASSESSMENT
The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant’s products are identical to the cross-reference products. Extensive clinical experience with nicotine is considered to have demonstrated the therapeutic value of the compound. The benefit/risk assessment is, therefore, considered to be positive.
Nicotine 1 mg Compressed Lozenge
Nicotine 2 mg Compressed Lozenge

PL 00030/0463-0468

STEPS TAKEN FOR ASSESSMENT

1 The MHRA received the Marketing Authorisation applications on 10 September 2012.

2 Following standard checks and communication with the applicant the MHRA considered the applications valid on 16 October 2012.

3 Following assessment of the applications the MHRA requested further information relating to the dossiers on 02 December 2012, 15 March 2013, 14 October 2013, 03 April 2014 and 05 August 2014,

4 The applicant responded to the MHRA’s request, providing further information on the 14 February 2013, 31 July 2013, 15 March 2013, 10 March 2014, 09 May 2014 and 16 October 2014.

5 The applications were granted on 15 January 2015.
SUMMARY OF PRODUCT CHARACTERISTICS

In accordance with Directive 2010/84/EU, the Summaries of Product Characteristics (SmPCs) for products granted Marketing Authorisations at a national level are available on the MHRA website.
PATIENT INFORMATION LEAFLET

In accordance with Directive 2010/84/EU, the Patient Information Leaflets (PILs) for products granted Marketing Authorisations at a national level are available on the MHRA website.
LABELLING

The Marketing Authorisation Holder has submitted the text version only and has committed to submitting mock-up livery to the relevant regulatory authorities for approval before packs are marketed. Please find below representative labelling for PL 00030/0463 and 0464. The labelling for all other product licences is consistent with these.

Nicotine 1 mg Compressed Lozenge (PL 00030/0463):

1. NAME OF THE MEDICINAL PRODUCT

Nicotine 1 mg Compressed Lozenge

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each compressed lozenge contains 1 mg nicotine (as nicotine bitartrate dihydrate)

3. LIST OF EXCIPIENTS

Maltitol (E965), aspartame (E951), sodium (9.8 mg per lozenge).
Read the leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Compressed lozenge
12, 36, 72, 96, 144 or 204 compressed lozenges in blister packs

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the sight and reach of children.
7. OTHER SPECIAL WARNING(S), IF NECESSARY

Do not use more than thirty 1 mg lozenges per day.
Do not chew or swallow the lozenge.
Do not take more than the amount recommended.

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Take it to the nearest pharmacy for safe disposal.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Novartis Consumer Health UK Limited
Park View, Riverside Way
Watchmoor Park, Camberley
Surrey GU15 3YL

12. MARKETING AUTHORISATION NUMBER(S)

PL 00030/0463

13. BATCH NUMBER

Lot
14. **GENERAL CLASSIFICATION FOR SUPPLY**

GSL

15. **INSTRUCTIONS ON USE**

How to suck the lozenge
Suick a lozenge until the taste becomes strong.
Rest the lozenge between your gums and cheek.
Suick again when the taste has faded.
Repeat this routine until the lozenge dissolves completely (about 30 minutes).

16. **INFORMATION IN BRAILLE**

Nicotine 1 mg Compressed Lozenge
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<th>MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS</th>
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<td>BLISTER</td>
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<td>1. <strong>NAME OF THE MEDICINAL PRODUCT</strong></td>
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<td>Nicotine 1 mg Compressed Lozenge</td>
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<td>2. <strong>NAME OF THE MARKETING AUTHORISATION HOLDER</strong></td>
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<td>Novartis Consumer Health</td>
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<td>3. <strong>EXPIRY DATE</strong></td>
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<td>EXP:</td>
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<td>4. <strong>BATCH NUMBER</strong></td>
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<td>5. <strong>OTHER</strong></td>
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Nicotine 2 mg Compressed Lozenge (PL 00030/0464):

PARTICULARS TO APPEAR ON THE OUTER PACKAGING CARTON

1. NAME OF THE MEDICINAL PRODUCT

Nicotine 2 mg Compressed Lozenge

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each compressed lozenge contains 2 mg nicotine (as nicotine bitartrate dihydrate)

3. LIST OF EXCIPIENTS

Malitol (E965), aspartame (E951), sodium (9.8 mg per lozenge).

Read the leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

Compressed lozenge

12, 36, 72, 96, 144 or 204 compressed lozenges in blister packs

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the sight and reach of children.
7. **OTHER SPECIAL WARNING(S), IF NECESSARY**

Do not use more than fifteen 2 mg lozenges per day.
Do not chew or swallow the lozenge.
Do not take more than the amount recommended.

8. **EXPIRY DATE**

EXP

9. **SPECIAL STORAGE CONDITIONS**

Do not store above 25°C

10. **SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPLICABLE**

Take it to the nearest pharmacy for safe disposal.

11. **NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Novartis Consumer Health UK Limited
Park View, Riverside Way
Watchmoor Park, Camberley
Surrey GU15 3YL

12. **MARKETING AUTHORISATION NUMBER(S)**

PL 00030/0464

13. **BATCH NUMBER**

Lot
14. GENERAL CLASSIFICATION FOR SUPPLY

GSL

15. INSTRUCTIONS ON USE

How to suck the lozenge
Suck a lozenge until the taste becomes strong.
Rest the lozenge between your gums and cheek.
Suck again when the taste has faded.
Repeat this routine until the lozenge dissolves completely (about 30 minutes).

16. INFORMATION IN BRAILLE

Nicotine 2 mg Compressed Lozenge
MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

**BLISTER**

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