Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nicotinell Mint 1 mg compressed lozenge

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each piece of lozenge contains:
Active substance: 1 mg nicotine (corresponding to 3.072 mg nicotine bitartrate dihydrate).

Excipients with known effect: aspartame and maltitol

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Compressed lozenge

Product imported from France:
White, mint flavoured, round biconvex lozenge

4 CLINICAL PARTICULARS

As per PA25456/001/004

5 PHARMACOLOGICAL PROPERTIES

As per PA25456/001/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maltitol (E965)
Sodium carbonate anhydrous
Sodium hydrogen carbonate
Polyacrylate dispersion 30 per cent
Xanthan gum
Colloidal anhydrous silica
Levomenthol
Peppermint oil
Aspartame (E951)
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the container and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

96 lozenges in blisters.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.,
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/261/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th June 2026

10 DATE OF REVISION OF THE TEXT