

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nicorette 2 mg Medicated Chewing-gum

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each piece of mediated chewing gum contains 2 mg nicotine as a resin complex.

Excipients with known effect:

Butylated hydroxytoluene

Sorbitol

Flavour for smoker (contains Cinnamal, Cinnamyl alcohol, Citral, Citronellol, Eugenol, Geraniol, Isoeugenol, Limonene, Linalool) ethanol

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Medicated Chewing-gum

Product imported from France:

A square, beige medicated chewing-gum

4 CLINICAL PARTICULARS

As per PA23490/019/014

5 PHARMACOLOGICAL PROPERTIES

As per PA23490/019/014

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

chewing gum

sorbitol (E420)

70% crystallizable sorbitol

anhydrous sodium carbonate

Sodium bicarbonate

smoking flavor (contains traces of ethanol, cinnamal, cinnamyl alcohol, citral, decitronellol, eugenol, geraniol, isoeugenol, limonene, linalool)

haverstroo flavor

glycerol 85 percent

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.

6.5 Nature and contents of container

Blister packed strips each containing 15 pieces supplied in packs of 105 and 210 pieces.

6.6 Special precautions for disposal

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

PPA1463/210/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th July 2024

10 DATE OF REVISION OF THE TEXT