

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nicorette Freshmint 4 mg Medicated Chewing Gum

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each medicated chewing gum contains 4 mg nicotine as a resin complex.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Medicated Chewing Gum.

Product imported from France:

A square, coated, cream coloured chewing gum.

4 CLINICAL PARTICULARS

As per PA23490/019/002

5 PHARMACOLOGICAL PROPERTIES

As per PA23490/019/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:

Chewing gum base

Xylitol

Peppermint essential oil

Anhydrous sodium carbonate

Acesulfame potassium

Levomenthol

Light magnesium oxide

Quinoline yellow aluminum lake (E104).

Coating:

Xylitol

Peppermint essential oil

Gum Arabic

Titanium dioxide (E171)

Carnauba wax

Quinoline yellow aluminum lake (E104).

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 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

PPA1463/210/010

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of authorisation: 19th July 2024

10 DATE OF REVISION OF THE TEXT