

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nicorette 4mg Medicated Chewing-gum

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients with known effect:

Each piece contains Sorbitol (E420) and Butylhydroxytoluene (E321).

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Medicated Chewing-gum

Product imported from the UK:

A square, yellow medicated chewing-gum

4 CLINICAL PARTICULARS

As per PA0823/049/004

5 PHARMACOLOGICAL PROPERTIES

As per PA0823/049/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chewing gum base (contains Butylhydroxytoluene (E321))

Sorbitol (E420)

Sodium carbonate

Quinoline yellow (E104)

Flavourings

Polacrillin

Glycerol

Talc

6.2 Incompatibilities

None known.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the container and outer package of the product on the market 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 30 or 210 pieces.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/187/006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27th October 2017

10 DATE OF REVISION OF THE TEXT