Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nicorette Invisi 15mg/16 hours Transdermal Patch

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Nicotine, 15 mg released over 16 hours use. Each patch is 13.5 cm^2, containing 1.75 mg nicotine/cm^2

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Transdermal patch

Product imported from France.

Beige, semi-transparent transdermal patch consisting of a backing layer, a nicotine source layer, a skin contact adhesive layer and a siliconised and aluminised release layer, with "nicorette" printed on the top face of the patch.

4 CLINICAL PARTICULARS

As per PA23490/019/006

5 PHARMACOLOGICAL PROPERTIES

As per PA23490/019/006

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyethylene terephthalate (PET) film
Triglycerides, medium-chain
Basic butyl methacrylate copolymer

Acrylate Matrix
Acrylic copolymer adhesive solution
Potassium hydroxide
Croscarmellose sodium
Aluminium acetylacetonate

Release Liner
Polyethylene terephthalate film (PET) film single side aluminised, both sides siliconised.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the sachet 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

Heat-sealed laminate pouch containing one patch.

Carton of 7 patches.

6.6 Special precautions for disposal

Nicotine residues in used patches may present a hazard to children and pets, thus used patches should be folded, sticky sides together, put back in an empty pouch and placed in household rubbish.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon Pharmaceuticals (Ireland) Limited
Block 3
Harcourt Centre
Harcourt Road
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/051/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th September 2022

10 DATE OF REVISION OF THE TEXT

November 2024