

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Noriday 350 micrograms tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 350 micrograms norethisterone.

Excipients with known effect: contains lactose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet
Product imported from the United Kingdom:
White, round, flat tablet with bevelled edges, inscribed "SEARLE" on one side and "NY" on the other.

4 CLINICAL PARTICULARS

As per PA0822/131/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/131/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Povidone
Magnesium stearate
Lactose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the blister strip and outer carton of the product on the market 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

Cardboard outer containing blister strip.
Pack size 28 tablets.

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. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2,
North Ring Business Park,
Santry,
Dublin 9,
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/220/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th February 2015.

10 DATE OF REVISION OF THE TEXT