

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Noriday 350 micrograms tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 350 micrograms norethisterone.

Excipient(s) with known effect:

contains lactose monohydrate

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet

Product imported from the UK

White, round, flat tablets 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 PA 0822/131/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch

Povidone

Magnesium stearate

Lactose monohydrate

6.2 Incompatibilities

Not applicable.

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. Store in the original package in order to protect from light and moisture.

6.5 Nature and contents of container

Nature and contents of container

Noriday tablets are supplied in PVC/foil blister packs of 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.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/310/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd August 2013
Last updated: January 2017

10 DATE OF REVISION OF THE TEXT

November 2019