

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: Also contains lactose.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet

Product imported from UK:

White, round, flat tablets with beveled edges, approximately 7/32" diameter, 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
Polyvidone
Magnesium stearate
Lactose

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 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. Store in a cool dry place away from direct sunlight.

6.5 Nature and contents of container

Noriday tablets are supplied in PVC/foil blister packs of 28 tablets inside a re-boxed package.

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

IMED Healthcare Ltd
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1463/073/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th October 2012

10 DATE OF REVISION OF THE TEXT

January 2015