

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Activelle 1 mg/0.5 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:

Estradiol 1 mg (as estradiol hemihydrate) and norethisterone acetate 0.5 mg.

Excipient with known effect: lactose (as monohydrate).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from Italy, Poland and Czech Republic:

White, film-coated, round tablets with a diameter of 6 mm, engraved with 'NOVO 288' on one side and the *Novo Nordisk* bull logo on the other.

4 CLINICAL PARTICULARS

As per PA0218/052/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0218/052/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Lactose monohydrate

Maize starch

Copovidone

Talc

Magnesium stearate

Film-coating:

Hypromellose

Triacetin

Talc

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. Do not refrigerate. Keep the container in the outer carton in order to protect from light.

6.5 Nature and contents of container

1 x 28 tablets in a calendar dial pack.

6.6 Special precautions for disposal and other handling

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/199/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th October 2007

10 DATE OF REVISION OF THE TEXT

October 2023