

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Femara 2.5 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: letrozole.

Each film coated tablet contains 2.5 mg letrozole.

Excipient of known effect: contains lactose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from Italy and Czech Republic:

Film-coated tablet, dark yellow, round, slightly biconvex with bevelled edges. One side bears the imprint "FV", the other "CG".

4 CLINICAL PARTICULARS

As per PA0896/012/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0896/012/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Cellulose microcrystalline
Maize starch
Sodium starch glycolate
Magnesium stearate
Silica colloidal anhydrous.

Coating:
Hypromellose
Talc
Macrogol 8000
Titanium dioxide (E171)
Iron oxide yellow (E172).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 30°C.

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

6.5 Nature and contents of container

Blister strips of 10 tablets in an overlabelled outer carton

Pack size: 30 tablets

6.6 Special precautions for disposal and other handling

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

PPA0465/303/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th January 2013

10 DATE OF REVISION OF THE TEXT

June 2020