

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Femara 2.5 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 2.5 mg letrozole.

Excipient(s) with known effect: lactose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets

Product imported from Czech Republic

Film-coated tablet, dark yellow, round, slightly biconvex. 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

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 is the date shown on the blister and outer package of the product as marketed 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

Blisters packs: 30 tablets per pack, 10 tablets per blister strip.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Originalis B.V.
Joop Geesinkweg 901
1114 AB Amsterdam-Duivendrecht
Netherlands

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th September 2018

10 DATE OF REVISION OF THE TEXT

October 2019