

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(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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/137/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th September 2020

10 DATE OF REVISION OF THE TEXT