

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Efexor XL 150 mg hard prolonged-release capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard prolonged-release capsule contains 169.7mg of venlafaxine hydrochloride equivalent to 150mg of venlafaxine free base.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Hard prolonged-release capsule.

Product imported from the United Kingdom:

Opaque dark orange capsules printed in white with 'W' and '150', hard gelatin capsule

4 CLINICAL PARTICULARS

As per PA0822/072/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/072/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule contents:

Microcrystalline cellulose
Ethylcellulose
Hypromellose
Talc

Capsule shell:

Gelatin
Red and yellow iron oxides (E172)
Titanium dioxide (E171)

Capsule printing ink:

Shellac
Propylene glycol
Sodium hydroxide
Povidone
Titanium dioxide (E171)

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 carton of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Two blister packs presented in an over labelled outer carton. Pack size of 28 prolonged release capsules.

6.6 Special precautions for disposal

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

PPA1463/075/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st February 2013

10 DATE OF REVISION OF THE TEXT

November 2021