

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Efexor XL 150 mg prolonged-release capsules, hard

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Efexor XL 150 mg;

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

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release capsule, hard

Product imported from Spain, the UK and Portugal:

Opaque dark-orange capsules printed in white with 'W' and '150'.

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

Yellow iron oxide (E172)

Red iron oxide (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 package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C.
Store in the original package.

6.5 Nature and contents of container

Blister packs containing 28 or 30 capsules.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

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

PPA0465/085/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

March 2020