

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Efexor XL 75 mg prolonged-release capsules, hard

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Efexor XL 75 mg;

Each prolonged-release capsule contains 84.85 mg of venlafaxine hydrochloride, equivalent to 75 mg 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, France, Italy and Greece

Opaque peach capsules printed in red with 'W' and '75' hard gelatin capsule, size 1

4 CLINICAL PARTICULARS

As per PA23355/002/002

5 PHARMACOLOGICAL PROPERTIES

As per PA23355/002/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from France, Spain, and Italy contains

Microcrystalline cellulose

Ethylcellulose

Hypromellose

Gelatin

Yellow iron oxide (E172)

Red iron oxide (E172)

Titanium dioxide (E171)

Product from France also contains

Black iron Oxide (E172)

Product from Spain also contains

Printing ink (shellac, propylene glycol, povidone, sodium hydroxide, titanium dioxide)

Product from Greece contains

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
Red iron oxide (E172)
Ammonium Hydroxide
Simethicone
Propylene Glycol

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

PPA0465/085/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

February 2020

10 DATE OF REVISION OF THE TEXT

September 2022