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 Greece:
Opaque peach capsules printed in red with 'W' and '75' hard gelatin capsule.

4 CLINICAL PARTICULARS

As per PA23355/002/002

5 PHARMACOLOGICAL PROPERTIES

As per PA23355/002/002

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
Red iron oxide (E172)
Ammonium hydroxide
Simeticone
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 30^{o}C.

6.5 Nature and contents of container

Blister packs containing 28 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

PPA1463/209/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th August 2023

10 DATE OF REVISION OF THE TEXT