

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 75mg hard prolonged-release capsules contain 75mg of venlafaxine as venlafaxine hydrochloride.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Hard prolonged-release capsule.

Product imported from Italy, Czech Republic & the UK.

Opaque peach capsules printed in red with 'W' on the cap and '75' on the body.

4 CLINICAL PARTICULARS

As per PA0822/072/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/072/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from Italy:

Microcrystalline cellulose
Ethylcellulose
Hypromellose
Gelatin
Yellow iron oxide (E172)
Red iron oxide (E172)
Titanium dioxide (E171)

Printing ink:

Pharmaceutical glaze
Red iron oxide (E172)
N-butyl alcohol
Isopropyl alcohol
Ammonium hydroxide
Simeticone
Propylene glycol

Product imported from Czech Republic and the UK:

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 for this product is the date shown on the blister strips and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Product imported from Italy

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

Product imported from Czech Republic:

Do not store above 30°C. Store in the original package in order to protect from light and moisture.

Product imported from the UK:

Do not store above 30°C.

6.5 Nature and contents of container

Cardboard outer containing blister strips.
Pack size: 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

PPA1463/146/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st July 2009

10 DATE OF REVISION OF THE TEXT

October 2020