

# 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 150mg hard prolonged-release capsules contain 150mg of venlafaxine as venlafaxine hydrochloride.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Prolonged-release capsule, hard.

*Product imported from Italy, Czech Republic & the UK.*

Opaque dark orange capsules printed in white with 'W' on the cap and '150' on the body.

## 4 CLINICAL PARTICULARS

As per PA0822/072/003

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0822/072/003

## 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:

Shellac  
Titanium dioxide (E171)  
n-butyl alcohol  
Isopropyl alcohol  
Ethyl alcohol  
Sodium hydroxide  
Povidone  
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  
Sodium hydroxide  
Povidone  
Titanium dioxide (E171)  
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:

Product imported from Italy:

30 capsules

Product imported from The Czech Republic & the UK:

28 capsules

Not all pack sizes may be marketed

**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**

PPA1463/146/002

**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