

# 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 169.7 mg of venlafaxine hydrochloride, equivalent to 150 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 Poland*

Opaque dark orange capsules printed in white with 'W' and '150', hard gelatin capsule, size 0 (23.5 mm x 7.65 mm).

## 4 CLINICAL PARTICULARS

As per PA23355/002/003

## 5 PHARMACOLOGICAL PROPERTIES

As per PA23355/002/003

## 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,

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 blister and outer carton of the product as marketed in the country of origin.

### **6.4 Special precautions for storage**

Do not store above 30 °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**

PCO Manufacturing Ltd.  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/085/005

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 1<sup>st</sup> August 2025

## **10 DATE OF REVISION OF THE TEXT**