

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Efexor XL 150mg Prolonged-Release Capsules, hard

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 169.7mg venlafaxine hydrochloride equivalent to 150mg venlafaxine.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release capsule, hard

Product imported from Italy & Spain:

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

Capsule contents:

Microcrystalline cellulose

Ethylcellulose

Hypromellose

Talc

Capsule shell:

Gelatin

Red and Yellow iron oxide (E172)

Titanium dioxide (E171)

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 for this product shall be 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

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

6.5 Nature and contents of container

Blister packs with push-through foil lidding, pack size 10.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

B & S Healthcare
Unit 4 Bradfield Road
Ruislip
Middlesex HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/118/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd October 2009

10 DATE OF REVISION OF THE TEXT

May 2015