Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Efexor XL 75mg prolonged release capsules, hard

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Efexor XL 75mg hard prolonged release capsules contain 84.85mg of venlafaxine hydrochloride, equivalent to 75mg of venlafaxine free base.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Hard prolonged release capsule

Product imported from Spain:
The capsules are hard gelatin capsule containing white to off-white spheroids of approximately 1 mm in diameter, peach colored, opaque with ‘W’ and ‘75’ printed in red.

Product imported from Italy:
Opaque peach capsules printed in red with "W" and "75" hard gelatine capsule size 1.

4 CLINICAL PARTICULARS

As per PA 0822/072/002

5 PHARMACOLOGICAL PROPERTIES

As per PA 0822/072/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product sourced from Italy:
microcrystalline cellulose,
ethyl cellulose,
hypromellose,
talc,
gelatin,
iron oxide red and yellow (E172),
titanium dioxide (E171),
shellac,
iron oxide red (E172),
ammonium hydroxide,
simethicone,
propylene glycol

Product sourced from Spain
Microcrystalline cellulose,
Ethylcellulose,
Hydroxypropylmethylcellulose,

Red Iron Oxide (E172), Yellow iron oxide (E172),
Titanium dioxide (E171),
Gelatin and
Printing ink
(Shellac,
N-butyl alcohol,
Isopropyl alcohol,
Propylene glycol,
Iron oxide (E172),
Ammonium hydroxide (28%),
Simethicone)

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

Product sourced from Italy: Store in the original packaging. Do not store above 25^{o}C.
Product sourced from Spain: Do not store above 30^{o}C.

6.5 Nature and contents of container

Blister packs with push through foil lidding, pack size 14 or 30.

Not all pack sizes may be available.

6.6 Special precautions for disposal and other handling

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

PPA1328/118/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd October 2009

10 DATE OF REVISION OF THE TEXT

November 2014