

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Prozac 20mg hard capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains fluoxetine hydrochloride equivalent to 20mg of fluoxetine.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Hard capsules.

Product imported from the UK:

The capsules are green and yellow, printed 'Lilly 3105'.

4 CLINICAL PARTICULARS

As per PA0047/077/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0047/077/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch flowable
Dimeticone

Capsule components:

Gelatin
Patent blue V (E131)
Yellow iron oxide (E172)
Titanium dioxide (E171)

Pharmaceutical grade edible printing ink, containing shellac, hydrated ferric oxide (black) E172, propylene glycol and may contain ammonium hydroxide and potassium hydroxide.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

PVC/aluminium blister packs of 30 capsules.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/091/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th October 2012

10 DATE OF REVISION OF THE TEXT

September 2017