

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Prozac 20 mg hard capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 20mg of fluoxetine (as fluoxetine hydrochloride).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Hard capsule.

Product imported from the UK

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

4 CLINICAL PARTICULARS

As per PA2276/004/002

5 PHARMACOLOGICAL PROPERTIES

As per PA2276/004/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch flowable

Dimeticone

Capsule components:

Patent blue V (E131)

Yellow iron oxide (E172)

Titanium dioxide (E171)

Gelatin

Black edible printing ink, which contains shellac, black iron oxide (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 of this product is the date shown on the blister strips and outer carton of the product as marked 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 hard capsules, presented in an outer cardboard carton.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
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Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/221/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd May 2014

10 DATE OF REVISION OF THE TEXT

October 2019