

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Prozac 20 mg hard capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Hard Capsules

Product imported from France, Italy, Spain & the Czech Republic.:

Hard capsules with pale yellow body and green cap, printed with 'Lilly 3105' on each part.

Product imported from the UK:

Hard capsules with pale yellow body and green cap, printed 'Prozac' on the body and '20 mg' on the cap.

4 CLINICAL PARTICULARS

As per PA2276/004/002

5 PHARMACOLOGICAL PROPERTIES

As per PA2276/004/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients in the product imported from the Netherlands, France, Belgium and Italy:

Maize starch

Dimeticone

Yellow iron oxide (E 172)

Titanium dioxide (E 171)

Gelatin

Patent blue V (E 131)

Excipients in the product imported from the Czech Republic:

Maize Starch

Dimeticone

Yellow iron oxide (E172)

Titanium dioxide (E171)

Gelatin

Patent blue V (E131)

Black edible printing ink

Excipients in the product imported from Spain:

Maize Starch

Dimeticone

Gelatin

Patent blue V (E131)

Yellow iron oxide (E172)

Titanium dioxide (E171)

Black edible ink including black iron oxide (E 172) and 2-ethoxyethanol

Excipients in the product imported from the UK:

Maize starch flowable

Dimeticone

Gelatin

Patent blue V (E131)

Yellow iron oxide (E172)

Titanium dioxide (E171)

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 for this product is 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

Do not store above 30 °C.

Keep the blisters in the outer carton.

6.5 Nature and contents of container

Blisters in strips in a cardboard carton.

Pack sizes: 14, 28 or 30 capsules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

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

PPA0465/040/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th October 1996

Date of last renewal: 10th October 2006

10 DATE OF REVISION OF THE TEXT

October 2019