

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Fluoxetine Aurobindo 20 mg capsules, hard

Fluoxetine Aurobindo 60 mg capsules, hard

fluoxetine hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each hard capsule contains 22.357 mg fluoxetine hydrochloride equivalent to 20 mg of Fluoxetine.

Each hard capsule contains 67.072 mg fluoxetine hydrochloride equivalent to 60 mg of Fluoxetine.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Capsule, hard

Blister pack

5 capsules, hard

7 capsules, hard

10 capsules, hard

14 capsules, hard

20 capsules, hard

28 capsules, hard

30 capsules, hard

56 capsules, hard

60 capsules, hard

Bottle pack

28 capsules, hard

500 capsules, hard

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING (S), IF NECESSARY

8. EXPIRY DATE

EXP:

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Fluoxetine Aurobindo 20 mg capsules, hard
Fluoxetine Aurobindo 60 mg capsules, hard

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTERS

1. NAME OF THE MEDICINAL PRODUCT

Fluoxetine Aurobindo 20 mg capsules, hard

Fluoxetine Aurobindo 60 mg capsules, hard

fluoxetine hydrochloride

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot:

5. OTHER

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE Label

1. NAME OF THE MEDICINAL PRODUCT

Fluoxetine Aurobindo 20 mg capsules, hard

Fluoxetine Aurobindo 60 mg capsules, hard

fluoxetine hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each hard capsule contains 22.357 mg fluoxetine hydrochloride equivalent to 20 mg of Fluoxetine.

Each hard capsule contains 67.072 mg fluoxetine hydrochloride equivalent to 60 mg of Fluoxetine.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Capsule, hard

28 capsules, hard

500 capsules, hard

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING (S), IF NECESSARY

8. EXPIRY DATE

EXP:

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE
