

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Cardboard box

1. NAME OF THE MEDICINAL PRODUCT

<Aripiprazole> 5 mg tablets
<Aripiprazole> 10 mg tablets
<Aripiprazole> 15 mg tablets
<Aripiprazole> 30 mg tablets

aripiprazole

2. STATEMENT OF ACTIVE SUBSTANCE(S)

<Aripiprazole> 5 mg: Each tablet contains 5 mg aripiprazole.
<Aripiprazole> 10 mg: Each tablet contains 10 mg aripiprazole.
<Aripiprazole> 15 mg: Each tablet contains 15 mg aripiprazole.
<Aripiprazole> 30 mg: Each tablet contains 30 mg aripiprazole.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

<tablet>

<Aripiprazole> 5 mg
<Aripiprazole> 30 mg

28 tablets
56 tablets
84 tablets

<Aripiprazole> 10 mg
<Aripiprazole> 15 mg

14 tablets
28 tablets
56 tablets
84 tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For 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

This medicinal product does not require any special temperature storage conditions.
Store in the original blister in order to protect from moisture.

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

<[To be completed nationally]>

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

<Aripiprazole> 5 mg tablets
<Aripiprazole> 10 mg tablets
<Aripiprazole> 15 mg tablets
<Aripiprazole> 30 mg tablets

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE MEDICINAL PRODUCT

<Aripiprazole> 5 mg tablets

<Aripiprazole> 10 mg tablets

<Aripiprazole> 15 mg tablets

<Aripiprazole> 30 mg tablets

aripiprazole

2. NAME OF THE MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER