

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON

1. NAME OF THE MEDICINAL PRODUCT

<Product name> 10 mg orodispersible tablets

<Product name> 15 mg orodispersible tablets

<Product name> 30 mg orodispersible tablets

aripiprazole

2. STATEMENT OF ACTIVE SUBSTANCE

Each tablet contains 10 mg of aripiprazole.

Each tablet contains 15 mg of aripiprazole.

Each tablet contains 30 mg of aripiprazole.

3. LIST OF EXCIPIENTS

Also contains aspartame (E951) and lactose.

See package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Orodispersible tablet

14 orodispersible tablets

28 orodispersible tablets

49 orodispersible tablets

14 x 1 orodispersible tablets

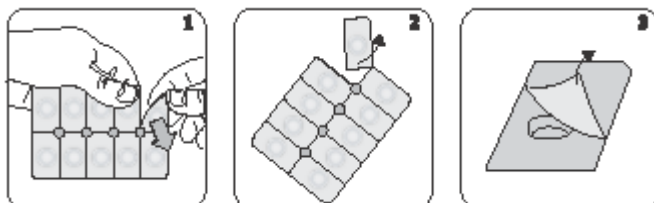
28 x 1 orodispersible tablets

49 x 1 orodispersible tablets

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

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

<Product name> 10 mg orodispersible tablets

<Product name> 15 mg orodispersible tablets

<Product name> 30 mg orodispersible tablets

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC: {number}

SN: {number}

NN: {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTERS

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<Product name> 15 mg orodispersible tablets

<Product name> 30 mg orodispersible tablets

aripiprazole

2. NAME OF THE MARKETING AUTHORISATION HOLDER

<To be completed nationally>

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER