

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

CARTON / BOTTLE

1. NAME OF THE MEDICINAL PRODUCT

Aripiprazole Orion 5 mg tablets
Aripiprazole Orion 10 mg tablets
Aripiprazole Orion 15 mg tablets
Aripiprazole Orion 30 mg tablets

aripiprazole

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 tablet contains: 5 mg aripiprazole,
1 tablet contains: 10 mg aripiprazole,
1 tablet contains: 15 mg aripiprazole,
1 tablet contains: 30 mg aripiprazole,

3. LIST OF EXCIPIENTS

lactose monohydrate.

4. PHARMACEUTICAL FORM AND CONTENTS

tablet

Blister packs:

14 tablets

28 tablets

56 tablets

98 tablets

HDPE bottles:

100 tablets

200 tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

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

Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

12. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

For outer carton only:

aripiprazole orion 5 mg
aripiprazole orion 10 mg
aripiprazole orion 15 mg
aripiprazole orion 30 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

For outer carton only:

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

For outer carton only:

PC: {number}

SN: {number}

NN: {number}, if applicable nationally

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Aripiprazole Orion 5 mg tablets
Aripiprazole Orion 10 mg tablets
Aripiprazole Orion 15 mg tablets
Aripiprazole Orion 30 mg tablets

aripiprazole

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Orion Corporation

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot:

5. OTHER