PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

<Product name> 5 mg tablets
<Product name> 10 mg tablets
<Product name> 15 mg tablets

Aripiprazole

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 5 mg of aripiprazole.
Each tablet contains 10 mg of aripiprazole.
Each tablet contains 15 mg of aripiprazole.

3. LIST OF EXCIPIENTS

Contains lactose. See package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Tablet

7 tablets
10 tablets
14 tablets
28 tablets
30 tablets
35 tablets
40 tablets
56 tablets
60 tablets
100 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

Store in the original package 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

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

PRO.MED.CS Praha a.s., Telčská 377/1, Michle, 140 00 Praha 4, Czech Republic

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> 5 mg
<Product name> 10 mg
<Product name> 15 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

<Product name> 5 mg tablets
<Product name> 10 mg tablets
<Product name> 15 mg tablets

Aripiprazole

2. NAME OF THE MARKETING AUTHORISATION HOLDER

PRO.MED.CS Praha a.s.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER