PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. NAME OF THE MEDICINAL PRODUCT

~~Deprilept~~[To be completed nationally], 10 mg f~~F~~ilm-coated tablets
~~Deprilept~~[To be completed nationally], 20 mg f~~F~~ilm-coated tablets

Escitalopram (as oxalate)

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 10 mg of escitalopram, equivalent to 12.77 mg of escitalopram oxalate.

Each film-coated tablet contains 20 mg of escitalopram, equivalent to 25.54 mg of escitalopram oxalate.

3. LIST OF EXCIPIENTS

Contains also lactose monohydrate. See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablet.
14 film-coated tablets
20 film-coated tablets
28 film-coated tablets
30 film-coated tablets
50film-coated tablets
56 film-coated tablets
100 film-coated 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

Kommentiert [JJ1]: Please use wording as in SmPC

Formatiert: Hervorheben

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

Ranbaxy (Poland) Sp. z o.o.
11 Kubickiego Street 02 - 954 Warsaw, Poland

12. MARKETING AUTHORISATION NUMBER(S)

10mg: 22860
20mg: 22861

13. BATCH NUMBER

Batch~~:~~

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

Space for the prescribed dose application by the pharmacist

Formatiert: Hervorheben

16. INFORMATION IN BRAILLE

~~Deprilept~~[To be completed nationally], 10 mg
~~Deprilept~~[To be completed nationally], 20 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

<2D barcode carrying the unique identifier included.>[1]

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA[1]

-PC: {number} ~~[product code]~~
SN: {number} ~~[serial number]~~
NN: {number} ~~[national reimbursement number or other national number identifying the medicinal product]~~

[1] ~~To be implemented not later than 9 February 2019~~

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{Polyamide/Aluminium/PVC/Aluminium Blisters }

1. NAME OF THE MEDICINAL PRODUCT

~~Deprilept~~[To be completed nationally], 10 mg ~~F~~ilm-coated tablets
~~Deprilept~~[To be completed nationally], 20 mg ~~F~~ilm-coated tablets

Escitalopram (as oxalate)

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Ranbaxy

3. EXPIRY DATE

Exp~~.~~:

4. BATCH NUMBER

Batch~~:~~

5. OTHER