PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND IMMEDIATE PACKAGING

CARTON FOR PVC/PE/PCTFE/ALU BLISTER, ALU/PA/ALU/PVC BLISTER AND HDPE/PP BOTTLE
LABEL FOR HDPE/PP BOTTLE

1. NAME OF THE MEDICINAL PRODUCT

[Nationally completed name] 30 mg gastro-resistant capsules, hard
[Nationally completed name] 60 mg gastro-resistant capsules, hard

Duloxetine (as hydrochloride)

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each capsule contains 30 mg of duloxetine (as hydrochloride).

Each capsule contains 60 mg of duloxetine (as hydrochloride).

3. LIST OF EXCIPIENTS

30 mg:
Contains lactose, Brilliant Blue FCF (E 133) and Allura Red (E 129).

60 mg:
Contains lactose, Sunset Yellow FCF (E 110), Brilliant Blue FCF (E 133) and Allura Red (E 129).

See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Blister:
7 gastro-resistant capsules, hard
14 gastro-resistant capsules, hard
28 gastro-resistant capsules, hard
30 gastro-resistant capsules, hard
50 gastro-resistant capsules, hard
56 gastro-resistant capsules, hard
84 gastro-resistant capsules, hard
98 gastro-resistant capsules, hard

HDPE/PP bottle:
30 gastro-resistant capsules, hard

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Oral 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

Storage conditions after first opening of the bottle:
After first opening, use within 30 days.

9. SPECIAL STORAGE CONDITIONS

Do not store above 30º C.

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

[To be completed nationally]

15. INSTRUCTIONS ON USE

[To be completed nationally]

16. INFORMATION IN BRAILLE

[To be completed nationally]

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

[To be completed nationally]

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC: {number}
SN: {number}
NN: {number}

[To be completed nationally]

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

PVC/PE/PCTFE/ALU BLISTER, ALU/PA/ALU/PVC BLISTER

1. NAME OF THE MEDICINAL PRODUCT

[Nationally completed name] 30 mg gastro-resistant capsules, hard
[Nationally completed name] 60 mg gastro-resistant capsules, hard

Duloxetine (as hydrochloride)

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER