

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton for blisters, Carton for HDPE bottle, label for HDPE bottle

1. NAME OF THE MEDICINAL PRODUCT

<Product name> 75 mg hard capsules

<Product name> 150 mg hard capsules

<Product name> 300 mg hard capsules

Pregabalin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each hard capsule contains 75 mg pregabalin.

Each hard capsule contains 150 mg pregabalin.

Each hard capsule contains 300 mg pregabalin.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Hard capsules

PVC/Al blister containing:

14

21

56

60

84

HDPE bottle containing:

30

200

500

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

14. GENERAL CLASSIFICATION FOR SUPPLY

<[To be completed nationally]>

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

<Product name> 75 mg

<Product name> 150 mg

<Product name> 300 mg

<not applicable> for HDPE bottle label

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

1. NAME OF THE MEDICINAL PRODUCT

<Product name> 75 mg hard capsules

<Product name> 150 mg hard capsules

<Product name> 300 mg hard capsules

2. NAME OF THE MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER