

**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**