

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

{CARTON FOR BLISTER PACK}

**1. NAME OF THE MEDICINAL PRODUCT**

{Invented name} 25 mg capsule, hard  
{Invented name} 50 mg capsule, hard  
{Invented name} 75 mg capsule, hard  
{Invented name} 100 mg capsule, hard  
{Invented name} 150 mg capsule, hard  
{Invented name} 200 mg capsule, hard  
{Invented name} 225 mg capsule, hard  
{Invented name} 300 mg capsule, hard

Pregabalin

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

Each hard capsule contains 25 mg of pregabalin.  
Each hard capsule contains 50 mg of pregabalin  
Each hard capsule contains 75 mg of pregabalin  
Each hard capsule contains 100 mg of pregabalin  
Each hard capsule contains 150 mg of pregabalin  
Each hard capsule contains 200 mg of pregabalin  
Each hard capsule contains 225 mg of pregabalin  
Each hard capsule contains 300 mg of pregabalin

**3. LIST OF EXCIPIENTS**

See leaflet for further information.

**4. PHARMACEUTICAL FORM AND CONTENTS**

Capsule, hard  
14 capsules, hard  
20 capsules, hard  
28 capsules, hard  
50 capsules, hard  
56 capsules, hard  
96 capsules, hard

**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 below 30°C.  
Store in the original package in order to protect from light.

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**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**

**16. INFORMATION IN BRAILLE**

{Invented name} 25 mg capsule, hard  
{Invented name} 50 mg capsule, hard  
{Invented name} 75 mg capsule, hard  
{Invented name} 100 mg capsule, hard  
{Invented name} 150 mg capsule, hard  
{Invented name} 200 mg capsule, hard  
{Invented name} 225 mg capsule, hard  
{Invented name} 300 mg capsule, hard

#### **17. UNIQUE IDENTIFIER – 2D BARCODE**

2D barcode carrying the unique identifier included.

**Formatiert:** Tabstopps: 1 cm, Links

#### **18. UNIQUE IDENTIFIER – HUMAN READABLE DATA**

PC: {number}

SN: {number}

NN: {number}

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**{ BLISTER FOR CAPSULES }**

**1. NAME OF THE MEDICINAL PRODUCT**

{Invented name} 25 mg capsule, hard  
{Invented name} 50 mg capsule, hard  
{Invented name} 75 mg capsule, hard  
{Invented name} 100 mg capsule, hard  
{Invented name} 150 mg capsule, hard  
{Invented name} 200 mg capsule, hard  
{Invented name} 225 mg capsule, hard  
{Invented name} 300 mg capsule, hard

Pregabalin

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

[To be completed nationally]

**3. EXPIRY DATE**

EXP:

**4. BATCH NUMBER**

Lot:

**5. OTHER**