

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 }

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{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