

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton of blister pack (10, 14, 20, 21, 28, 30, 56, 60, 70 (for 75 mg only) 84, 90, 100) and multipacks (84, 112, 120, 200) for 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, 300 mg capsules, hard

1. NAME OF THE MEDICINAL PRODUCT

[xxx] 25 mg capsules, hard
[xxx] 50 mg capsules, hard
[xxx] 75 mg capsules, hard
[xxx] 100 mg capsules, hard
[xxx] 150 mg capsules, hard
[xxx] 200 mg capsules, hard
[xxx] 225 mg capsules, hard
[xxx] 300 mg capsules, hard
Pregabalin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

[xxx] 25 mg capsules, hard
Each hard capsule contains 25 mg pregabalin.
[xxx] 50 mg capsules, hard
Each hard capsule contains 50 mg pregabalin.
[xxx] 75 mg capsules, hard
Each hard capsule contains 75 mg pregabalin.
[xxx] 100 mg capsules, hard
Each hard capsule contains 100 mg pregabalin.
[xxx] 150 mg capsules, hard
Each hard capsule contains 150 mg pregabalin.
[xxx] 200 mg capsules, hard
Each hard capsule contains 200 mg pregabalin
[xxx] 225 mg capsules, hard
Each hard capsule contains 225 mg pregabalin.
[xxx] 300 mg capsules, hard
Each hard capsule contains 300 mg pregabalin.

3. LIST OF EXCIPIENTS

This product contains lactose monohydrate: see the package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

10 capsules, hard
14 capsules, hard
20 capsules, hard
21 capsules, hard
28 capsules, hard
30 capsules, hard
56 capsules, hard
60 capsules, hard
70 capsules, hard [for 75 mg only]

84 capsules, hard
90 capsules, hard
100 capsules, hard
Multipack: 84 (2 packs of 42) capsules, hard
Multipack: 112 (2 packs of 56) capsules, hard
Multipack: 120 (2 packs of 60) capsules, hard
Multipack: 200 (2 packs of 100) capsules, hard
[For multipacks only]:
Component of a multipack, can't be sold separately.

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

Batch:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

- [XXX] 25 mg
- [XXX] 50 mg
- [XXX] 75 mg
- [XXX] 100 mg
- [XXX] 150 mg
- [XXX] 200 mg
- [XXX] 225 mg
- [XXX] 300 mg

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister pack

1. NAME OF THE MEDICINAL PRODUCT

[xxx] 25 mg capsules, hard
[xxx] 50 mg capsules, hard
[xxx] 75 mg capsules, hard
[xxx] 100 mg capsules, hard
[xxx] 150 mg capsules, hard
[xxx] 200 mg capsules, hard
[xxx] 225 mg capsules, hard
[xxx] 300 mg capsules, hard
Pregabalin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Batch:

5. OTHER