

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER PACKING

1. NAME OF THE MEDICINAL PRODUCT

[Product name] 50 mg prolonged-release tablets
[Product name] 150 mg prolonged-release tablets
[Product name] 200 mg prolonged-release tablets
[Product name] 300 mg prolonged-release tablets
[Product name] 400 mg prolonged-release tablets
Quetiapine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged-release tablet contains 50 mg of quetiapine (as quetiapine fumarate)
Each prolonged-release tablet contains 150 mg of quetiapine (as quetiapine fumarate)
Each prolonged-release tablet contains 200 mg of quetiapine (as quetiapine fumarate)
Each prolonged-release tablet contains 300 mg of quetiapine (as quetiapine fumarate)
Each prolonged-release tablet contains 400 mg of quetiapine (as quetiapine fumarate)

3. LIST OF EXCIPIENTS

Contains lactose. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release tablets

10 prolonged-release tablets
30 prolonged-release tablets
50 prolonged-release tablets
56 prolonged-release tablets
60 prolonged-release tablets
100 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Do not split, chew or crush the tablets
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

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

<To be completed nationally>

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[Product name] 50mg prolonged-release tablets
[Product name] 150mg prolonged-release tablets
[Product name] 200mg prolonged-release tablets
[Product name] 300mg prolonged-release tablets
[Product name] 400mg prolonged-release tablets

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blisters

1. NAME OF THE MEDICINAL PRODUCT

[Product name] 50 mg prolonged-release tablets

[Product name] 150 mg prolonged-release tablets

[Product name] 200 mg prolonged-release tablets

[Product name] 300 mg prolonged-release tablets

[Product name] 400 mg prolonged-release tablets

Quetiapine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER