

## **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**