

## **LABELLING**

### **PACKAGING (outer package)**

#### **PARTICULARS TO APPEAR ON THE OUTER PACKAGING - CARTON**

##### **1. NAME OF THE MEDICINAL PRODUCT**

[Nationally approved name] 5 mg film-coated tablets

Active substance: Escitalopram

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

Each film-coated tablet contains 5 mg escitalopram (as oxalate).

##### **3. LIST OF EXCIPIENTS**

Contains sodium traces.  
Read the package leaflet before use.

##### **4. PHARMACEUTICAL FORM AND CONTENTS**

7 film-coated tablets  
10 film-coated tablets  
14 film-coated tablets  
15 film-coated tablets  
20 film-coated tablets  
28 film-coated tablets  
30 film-coated tablets  
50 film-coated tablets  
56 film-coated tablets  
60 film-coated tablets  
98 film-coated tablets  
100 film-coated tablets

##### **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**

Lot:

**14. GENERAL CLASSIFICATION FOR SUPPLY**

[To be completed nationally]

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

[To be completed nationally]

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

<2D barcode carrying the unique identifier included.>

**18. UNIQUE IDENTIFIER - HUMAN READABLE DATA**

PC: {number}

SN: {number}

NN: {number}

## **LABELLING**

### **MINIMUM PARTICULARS TO APPEAR ON BLISTERS**

#### **1. NAME OF THE MEDICINAL PRODUCT**

[Nationally approved name] 5 mg film-coated tablets  
Escitalopram

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

[To be completed nationally]

#### **3. EXPIRY DATE**

EXP:

#### **4. BATCH NUMBER**

Lot:

#### **5. OTHER**