

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING**

**CARTON BOX**

**1. NAME OF THE MEDICINAL PRODUCT**

/.../ 100 mg film-coated tablets

sildenafil

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

Each tablet contains sildenafil citrate equivalent to 100 mg of sildenafil.

**3. LIST OF EXCIPIENTS**

Contains also traces of sodium.  
See package leaflet for further information.

**4. PHARMACEUTICAL FORM AND CONTENTS**

Film-coated tablet.

1 film-coated tablet  
2 film-coated tablets  
4 film-coated tablets  
8 film-coated tablets  
10 film-coated tablets  
12 film-coated tablets  
20 film-coated tablets  
24 film-coated tablets  
28 film-coated tablets  
90 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**

/.../ 100 mg

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

2D barcode carrying the unique identifier included.

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

PC:

SN:

NN:

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**BLISTERS**

**1. NAME OF THE MEDICINAL PRODUCT**

/.../ 100 mg film-coated tablets

sildenafil

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

<To be completed nationally>

**3. EXPIRY DATE**

EXP

**4. BATCH NUMBER**

Lot

**5. OTHER**