

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

CARTON BOX

1. NAME OF THE MEDICINAL PRODUCT

/.../ 25/50/100 mg film-coated tablets

sildenafil

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains sildenafil citrate equivalent to 25 mg of sildenafil.

Each tablet contains sildenafil citrate equivalent to 50 mg of sildenafil.

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

3. LIST OF EXCIPIENTS

Contains lactose.

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

Medical product subject to medicinal prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

/.../ 25 mg
/.../ 50 mg
/.../ 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

/.../ 25/50/100 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