PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

[Invented name] 2.5 mg film-coated tablets
[Invented name] 5 mg film-coated tablets
[Invented name] 10 mg film-coated tablets
[Invented name] 20 mg film-coated tablets

tadalafil

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 2.5 mg tadalafil.
Each tablet contains 5 mg tadalafil.
Each tablet contains 10 mg tadalafil.
Each tablet contains 20 mg tadalafil.

3. LIST OF EXCIPIENTS

Contains lactose. See package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablet

2.5 mg
14 film-coated tablets
28 film-coated tablets
28x1 film-coated tablets
30 film-coated tablets
56 film-coated tablets

5 mg
14 film-coated tablets
14x1 film-coated tablets
18 film-coated tablets
28 film-coated tablets
28x1 film-coated tablets
30 film-coated tablets
84 film-coated tablets
84x1 film-coated tablets
98x1 film-coated tablets
112x1 film-coated tablets

10 mg
4 film-coated tablets
4x1 film-coated tablets
12 film-coated tablets

18 film-coated tablets
24x1 film-coated tablets
28 film-coated tablets

20 mg
2 film-coated tablets
2x1 film-coated tablets
4 film-coated tablets
4x1 film-coated tablets
5 film-coated tablets
8 film-coated tablets
8x1 film-coated tablets
10 film-coated tablets
12 film-coated tablets
12x1 film-coated tablets
15 film-coated tablets
18 film-coated tablets
24 film-coated tablets
24x1 film-coated tablets
28 film-coated tablets
36 film-coated tablets
36x1 film-coated tablets
48 film-coated tablets
56 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral 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

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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

[Invented name] 2.5 mg
[Invented name] 5 mg
[Invented name] 10 mg
[Invented name] 20 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

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

[Invented name] 2.5 mg film-coated tablets
[Invented name] 5 mg film-coated tablets
[Invented name] 10 mg film-coated tablets
[Invented name] 20 mg film-coated tablets

tadalafil

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER