

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Vesicare 1 mg/ml oral suspension
solifenacin succinate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 ml oral suspension contains 1 mg solifenacin succinate, equivalent to 0.75 mg solifenacin.

3. LIST OF EXCIPIENTS

Methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), ethanol, propylene glycol (E1520), benzoic acid (E210).

See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

150 ml oral suspension

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.

For oral use.

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP:

After first opening of the bottle, the product can be stored for 28 days.

9. SPECIAL STORAGE CONDITIONS

Store in the original bottle in order to protect from light.

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]>

<[See Annex I - To be completed nationally]> *[For referral procedures]*

{Name and Address}

<{tel}>

<{fax}>

<{e-mail}>

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

This medicine includes administration devices: 5 ml oral syringe and adaptor.

Please read the patient instruction leaflet before use

<[To be completed nationally]> *[For referral procedures]*

16. INFORMATION IN BRAILLE

<[To be completed nationally]> *[For referral procedures]*

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC: {number} [product code]

SN: {number} [serial number]

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BOTTLE

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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

Open date: _____

16. INFORMATION IN BRAILLE

<[To be completed nationally]> *[For referral procedures]*