**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**CARTON (5 mg)**

## 1. NAME OF THE MEDICINAL PRODUCT

<Product name> 5 mg
film-coated tablets
solifenacin succinate

## 2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 5 mg of solifenacin succinate, corresponding to 3.8 mg of solifenacin.

## 3. LIST OF EXCIPIENTS

Contains lactose monohydrate.

For further information see package leaflet.

## 4. PHARMACEUTICAL FORM AND CONTENTS

10 tablets
14 tablets
20 tablets
28 tablets
30 tablets
50 tablets
56 tablets
60 tablets
90 tablets
98 tablets
100 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**

<Product name> 5 mg

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

2D barcode carrying the unique identifier included.

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

PC:
SN:
NN:

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**CARTON (10 mg)**

**1. NAME OF THE MEDICINAL PRODUCT**

<Product name> 10 mg
film-coated tablets
solifenacin succinate

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

Each tablet contains 10 mg of solifenacin succinate, corresponding to 7.5 mg of solifenacin.

**3. LIST OF EXCIPIENTS**

Contains lactose monohydrate.

For further information see package leaflet.

**4. PHARMACEUTICAL FORM AND CONTENTS**

10 tablets
14 tablets
20 tablets
28 tablets
30 tablets
50 tablets
56 tablets
60 tablets
90 tablets
98 tablets
100 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**

<Product name> 10 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 (5 mg)**

**1. NAME OF THE MEDICINAL PRODUCT**

<Product name> 5 mg film-coated tablets
solifenacin succinate

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

[To be completed nationally]

**3. EXPIRY DATE**

EXP

**4. BATCH NUMBER**

*[Batch number will be printed during the packaging process.]*

**5. OTHER**

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

**BLISTER (10 mg)**

**1. NAME OF THE MEDICINAL PRODUCT**

<Product name> 10 mg film-coated tablets
solifenacin succinate

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

[To be completed nationally]

**3. EXPIRY DATE**

EXP

## 4. BATCH NUMBER

*[Batch number will be printed during the packaging process.]*

## 5. OTHER