PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

BOX FOR BLISTER AND BOTTLE
LABEL FOR BOTTLE

1. NAME OF THE MEDICINAL PRODUCT

[nationally completed name] 5 mg film-coated tablets
[nationally completed name] 10 mg film-coated tablets

solifenacin succinate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 5 mg of solifenacin succinate equivalent to 3.8 mg solifenacin.

Each film-coated tablet contains 10 mg of solifenacin succinate equivalent to 7.5 mg solifenacin.

3. LIST OF EXCIPIENTS

Contains among others: lactose.
See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

[PVC//Al blister]
10 film-coated tablets
20 film-coated tablets
30 film-coated tablets
90 film-coated tablets
100 film-coated tablets

[Polyethylene bottle (with a polypropylene screw cap/desiccant insert)]
30 film-coated tablets
56 film-coated tablets
60 film-coated tablets
84 film-coated tablets
90 film-coated tablets
100 film-coated tablets

754

250 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
[HDPE bottles:] Use within 6 months after first opening.

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)

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[To be completed nationally]

17. UNIQUE IDENTIFIER – 2D BARCODE

[only for the box]
2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

[only for the box]
PC {number}
SN {number}
NN {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
Blister

1. NAME OF THE MEDICINAL PRODUCT

[nationally completed name] 5 mg film-coated tablets
[nationally completed 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

Lot

5. OTHER