1.3 Product Information

1.3.1 SPC, labeling and package leaflet

1.3.1.2 Labelling text

Labelling text is presented on subsequent pages:

Labelling Details (English)

-Enclosed-

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

BLISTER/PVC-ALU BLISTER

1. NAME OF MEDICINAL PRODUCT

Spironolactone Accord 25mg film-coated tablets
Spironolactone
Spironolactone Accord 50mg film-coated tablets
Spironolactone
Spironolactone Accord 100mg film-coated tablets
Spironolactone

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Accord

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

-

PARTICULAR TO APPEAR ON THE OUTER PACKING

OUTER CARTON/ ALU-PVC BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Spironolactone Accord 25mg film-coated tablets
Spironolactone
Spironolactone Accord 50mg film-coated tablets
Spironolactone
Spironolactone Accord 100mg film-coated tablets
Spironolactone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 25 mg spironolactone.
Each film-coated tablet contains 50 mg spironolactone.
Each film-coated tablet contains 100 mg spironolactone.

3. LIST OF EXCEPIENTS

Contains lactose.
Read the package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

20 film-coated tablets
28 film-coated tablets
30 film-coated tablets
50 film-coated tablets
60 film-coated tablets
90 film-coated tablets
100 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMNINISTRATION

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

Store in the original package 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 ADRESS OF THE MARKETING AUTHORISATION HOLDER

Accord Healthcare Limited,
Sage House, 319 Pinner Road, North Harrow,
Middlesex, HA1 4HF,
United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

<To be competed nationally>

13. BATCH NUMBER

Lot

14. GENRAL CLASSIFICATION FOR SUPPLY

<To be competed nationally>

15. INSTRUACTION OF USE

-

16. INFORMATION IN BRAILLE

Spironolactone Accord 25mg
Spironolactone Accord 50mg
Spironolactone Accord 100mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC: {number}
SN: {number}
NN: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

{BOTTLE LABEL}

1. NAME OF THE MEDICINAL PRODUCT

Spironolactone Accord 25mg film-coated tablets
Spironolactone
Spironolactone Accord 50mg film-coated tablets
Spironolactone
Spironolactone Accord 100mg film-coated tablets
Spironolactone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 25 mg spironolactone.
Each film-coated tablet contains 50 mg spironolactone.
Each film-coated tablet contains 100 mg spironolactone.

3. LIST OF EXCIPIENTS

Contains lactose.
Read the package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablet

[Pack sizes for hospital or dose dispensing use only]
250 film-coated tablets
500 film-coated tablets
1000 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

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

Use within 3 months after first opening.

9. SPECIAL STORAGE CONDITIONS

Store in the original package 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.

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

[Not Applicable: pack sizes for hospital or dose dispensing use only]

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC: {number}
SN: {number}
NN: {number}