

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

BLISTER CARTON

1. NAME OF THE MEDICINAL PRODUCT

MORYSA 10 mg Film-coated Tablets

MORYSA 20 mg Film-coated Tablets

Memantine hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 10 mg memantine hydrochloride equivalent to 8.31 mg memantine

Each film-coated tablet contains 20 mg memantine hydrochloride equivalent to 16.62 mg memantine

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

28 Film-coated Tablets

42 Film-coated Tablets

56 Film-coated Tablets

98 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

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

Batch No.:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medicinal prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

MORYSA 10 mg Film-coated Tablets
MORYSA 20 mg Film-coated Tablets

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER LABEL

1. NAME OF THE MEDICINAL PRODUCT

MORYSA 10 mg Film-coated Tablets

MORYSA 20 mg Film-coated Tablets

Memantine hydrochloride

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

3. EXPIRY DATE

EXP.:

4. BATCH NUMBER

Batch No.:

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

HDPE CARTON / HDPE LABEL

1. NAME OF THE MEDICINAL PRODUCT

MORYSA 10 mg Film-coated Tablets
MORYSA 20 mg Film-coated Tablets

Memantine hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 10 mg memantine hydrochloride equivalent to 8.31 mg memantine

Each film-coated tablet contains 20 mg memantine hydrochloride equivalent to 16.62 mg memantine

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

30 Film-coated Tablets
100 Film-coated Tablets
500 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:

Do not use for more than 75 days after you first open it.

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

Batch No.:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medicinal prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE (Outer packaging only)

MORYSA 10 mg Film-coated Tablets

MORYSA 20 mg Film-coated Tablets