

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

COPAXONE 40 mg/ml
solution for injection in pre-filled syringe

glatiramer acetate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 pre-filled syringe (1 ml) contains 40 mg glatiramer acetate, equivalent to 36 mg of glatiramer.

3. LIST OF EXCIPIENTS

Mannitol, water for injections

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection in pre-filled syringe.

3 pre-filled syringes of 1 ml solution for injection
12 pre-filled syringes of 1 ml solution for injection

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

subcutaneous use
For single use only.

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 a refrigerator.

Do not freeze.

Keep the pre-filled syringes in the outer carton, 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

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

{Name and address }

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

COPAXONE 40 MG/ML

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

OUTER CARTON OF MULTIPACKS

1. NAME OF THE MEDICINAL PRODUCT

COPAXONE 40 mg/ml
solution for injection in pre-filled syringe

glatiramer acetate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 pre-filled syringe (1 ml) contains 40 mg glatiramer acetate, equivalent to 36 mg of glatiramer.

3. LIST OF EXCIPIENTS

Mannitol, water for injections

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection in pre-filled syringe.

36 (3 packs of 12) pre-filled syringes of 1 ml solution for injection

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

subcutaneous use
For single use only.

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 a refrigerator.

Do not freeze.

Keep the pre-filled syringes in the outer carton, 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

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

{Name and address }

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

COPAXONE 40 MG/ML

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

INTERMEDIATE CARTON OF MULTIPACKS

1. NAME OF THE MEDICINAL PRODUCT

COPAXONE 40 mg/ml
solution for injection in pre-filled syringe

glatiramer acetate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 pre-filled syringe (1 ml) contains 40 mg glatiramer acetate, equivalent to 36 mg of glatiramer.

3. LIST OF EXCIPIENTS

Mannitol, water for injections

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection in pre-filled syringe.

12 pre-filled syringes of 1 ml solution for injection. Component of a multipack, can't be sold separately.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

subcutaneous use
For single use only.

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 a refrigerator.

Do not freeze.

Keep the pre-filled syringes in the outer carton, 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

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]
{Name and address }

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

COPAXONE 40 MG/ML

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

NONTRANSPARENT BLISTER LID (nontransparent with printing)

TRANSPARENT BLISTER LID: (refer to syringe label for all minimum particulars)

1. NAME OF THE MEDICINAL PRODUCT

Nontransparent blister lid: COPAXONE 40 mg/ml

Pharmaceutical form and active substance: technically not feasible in all languages, refer to the syringe label

Transparent blister lid: refer to the syringe label

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Nontransparent blister lid: technically not feasible, refer to the syringe label

Transparent blister lid: refer to the syringe label

3. EXPIRY DATE

Nontransparent blister lid: technically not feasible, refer to the syringe label

Transparent blister lid: refer to the syringe label

4. BATCH NUMBER

Nontransparent blister lid: technically not feasible, refer to the syringe label

Transparent blister lid: refer to the syringe label

5. OTHER

Nontransparent blister lid: * 2° - 8°C

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL PRE-FILLED SYRINGE

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

COPAXONE 40 mg/ml
injection (patient-friendly short term in all languages)

glatiramer acetate

SC

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP

4. BATCH NUMBER

LOT

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

40 mg/1 ml

6. OTHER

TEVA (MAH)
MA number (if required for a member state)