

## **LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**CARTON PRE-FILLED PEN**

**1. NAME OF THE MEDICINAL PRODUCT**

COPAXONE PEN 40 mg  
solution for injection in pre-filled pen  
  
glatiramer acetate

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

1 ml of solution for injection (1pre-filled pen) contains 40 mg glatiramer acetate, equivalent to 36 mg of glatiramer.

**3. LIST OF EXCIPIENTS**

Excipients:

Mannitol, water for injections

**4. PHARMACEUTICAL FORM AND CONTENTS**

Solution for injection in pre-filled pen.

12 pre-filled pens of 1 ml solution for injection  
3 pre-filled pens of 1 ml solution for injection  
36 (3 packs of 12) pre-filled pens 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 pens in the outer carton, in order to protect from light.

For further information, see package leaflet.

**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]

{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 PEN 40 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**

**INTERMEDIATE CARTON OF MULTIPACKS**

**1. NAME OF THE MEDICINAL PRODUCT**

COPAXONE PEN 40 mg

solution for injection in pre-filled pen

glatiramer acetate

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

1 ml of solution for injection (1pre-filled pen) contains 40 mg glatiramer acetate, equivalent to 36 mg of glatiramer.

**3. LIST OF EXCIPIENTS**

Excipients:

Mannitol, water for injections

**4. PHARMACEUTICAL FORM AND CONTENTS**

Solution for injection in pre-filled pen.

12 pre-filled pens 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 pens in the outer carton, in order to protect from light.  
For further information, see package leaflet.

**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]  
{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 PEN 40 mg

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

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



**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**LABEL PRE-FILLED PEN**

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

COPAXONE PEN 40 mg  
injection

glatiramer acetate

SC

**2. METHOD OF ADMINISTRATION**

Read the package leaflet before use.

**3. EXPIRY DATE**

EXP

**4. BATCH NUMBER**

Lot

**5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT**

1 ml

**6. OTHER**

TEVA (MAH)

MA number (if required for a member state)