

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Copaxone 20 mg/ml Solution for Injection, Pre-filled Syringe

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of solution for injection contains 20 mg glatiramer acetate*, equivalent to 18 mg of glatiramer base per pre-filled syringe

* The average molecular weight of glatiramer acetate mixture is in the range of 5,000-9,000 daltons. Due to its compositional complexity, no specified polypeptide can be fully characterized in terms of amino acid sequence, although the final glatiramer acetate composition is not entirely random.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection in pre-filled syringe

Product imported from Greece

Clear solution free of visible particles

The solution for injection has a pH of 5.5 - 7.0 and an osmolarity of about 265 mOsmol/L.

4 CLINICAL PARTICULARS

As per PA1014/001/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1014/001/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol

Water for Injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on the container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Keep the pre-filled syringes in the outer carton, in order to protect from light.

Store in a refrigerator (2°C – 8°C).

Do not freeze.

If the pre-filled syringes cannot be stored in a refrigerator, they can be stored between 15°C and 25°C, once for up to

one month.

After this one month period, if the Copaxone 20 mg/ml pre-filled syringes have not been used and are still in their original packaging, they must be returned to storage in a refrigerator (2°C to 8°C).

6.5 Nature and contents of container

A pre-filled syringe containing Copaxone solution for injection consists of a 1 ml long colourless glass syringe barrel with staked needle, a plunger rod, a rubber plunger stopper and a needle shield.

Copaxone is available in packs containing 28 pre-filled syringes of 1 ml solution for injection.

6.6 Special precautions for disposal

For single use only. Any unused product or waste material must be discarded.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/432/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd November 2017

10 DATE OF REVISION OF THE TEXT