

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

* Glatiramer acetate is the acetate salt of synthetic polypeptides, containing four naturally occurring amino acids: L-glutamic acid, L-alanine, L tyrosine and L-lysine, in molar fraction ranges of 0.129-0.153, 0.392-0.462, 0.086-0.100 and 0.300-0.374, respectively. The average molecular weight of glatiramer acetate is in the range of 5,000-9,000 daltons. Due to its compositional complexity, no specific polypeptide can be fully characterised, including 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 Lithuania and Croatia

Clear solution free of visible particles.

The solution for injection has a pH of 5.5 - 7.0 and an osmolarity of about 300 mOsmol/L.

4 CLINICAL PARTICULARS

As per PA22579/001/002

5 PHARMACOLOGICAL PROPERTIES

As per PA22579/001/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol (E 421)

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 is the date shown on the blister and outer carton of the product as marketed 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 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 40 mg/ml solution for injection consists of a 1 ml colourless type I glass syringe barrel with staked needle, a blue polypropylene (optional polystyrene) plunger rod, a rubber plunger stopper and a needle shield. Each pre-filled syringe is packed separately in a PVC blister pack. Copaxone 40 mg/ml is available in packs containing 12 pre-filled syringes of 1 ml solution for injection.

6.6 Special precautions for disposal

For single use only. Any unused medical product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/432/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of authorisation: 15th July 2022

10 DATE OF REVISION OF THE TEXT

October 2022