Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Metoject 50 mg/ml Solution for Injection, pre-filled syringe

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of solution contains 50 mg methotrexate (as methotrexate disodium).
1 pre-filled syringe of 0.30 ml contains 15 mg methotrexate.
1 pre-filled syringe of 0.40 ml contains 20 mg methotrexate.
1 pre-filled syringe of 0.50 ml contains 25 mg methotrexate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection, pre-filled syringe.

Product imported from Greece
Clear, yellow-brown solution

4 CLINICAL PARTICULARS

As per PA0623/014/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0623/014/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Sodium hydroxide for pH adjustment
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

Store below 25 °C. Keep the pre-filled syringes in the outer carton in order to protect from light.

6.5 Nature and contents of container

Nature of container
Pre-filled syringes of colourless glass of 1 ml capacity with embedded injection needle.
Plunger stoppers and rods inserted on the stopper to form the syringe plunger.

Pack size

Pre-filled syringes containing 0.30 ml, 0.40 ml, or 0.50 ml solution are available in packs of 1 syringe with embedded s.c. injection needle and alcohol pads.

Pre-filled syringes containing 0.30 ml, 0.40 ml, or 0.50 ml solution are available in packs of 1 syringe with embedded s.c. injection needle.

All pack sizes are available with graduation marks.

6.6 Special precautions for disposal and other handling

The manner of handling and disposal must be consistent with that of other cytotoxic preparations in accordance with local requirements. Pregnant health care personnel should not handle and/or administer Metoject 50mg/ml Solution for Injection, pre-filled syringe.

Methotrexate should not come into contact with the skin or mucosa. In the event of contamination, the affected area must be rinsed immediately with ample amount of water.

For single use only.

Any unused medicinal 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

PPA0465/436/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th March 2019

10 DATE OF REVISION OF THE TEXT

November 2023