Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Metoject 20 mg solution for injection in pre-filled pen

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 pre-filled pen with 0.40 ml solution contains 20 mg methotrexate.

Excipients with known effect: sodium chloride and sodium hydroxide.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection in pre-filled pen.

Product imported from Czech Republic:
Clear, yellow-brown solution.

4 CLINICAL PARTICULARS

As per PA0623/014/005

5 PHARMACOLOGICAL PROPERTIES

As per PA0623/014/005

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Sodium hydroxide (for pH adjustment)
Hydrochloric acid (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 is the date shown on the container and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Store below 25 °C. Do not freeze.
Keep the pre-filled pens in the outer carton in order to protect from light.

6.5 Nature and contents of container

Pre-filled pens containing a colourless pre-filled syringe with plunger stopper and embedded injection needle. The syringe is externally equipped with the device for self-administration (pen).

Metoject pre-filled pen is available as a three-step auto-injector that has a yellow cap and a yellow injection button.

Pack size:
Pre-filled pens containing 0.4 ml (20 mg), solution are available in packs of 1 pre-filled pens.

The prefilled syringe within the pen may or may not have graduations on the barrel. These graduations are non-functional.

6.6 Special precautions for disposal

The manner of handling and disposal must be in accordance with local requirements. Pregnant health care personnel should not handle and/or administer Metoject.

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 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

PPA0465/436/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th April 2024

10 DATE OF REVISION OF THE TEXT