

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

MENOPUR 1200 IU Powder and Solvent for Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial with powder contains highly purified menotrophin (human menopausal gonadotrophin, HMG) corresponding to follicle stimulating hormone activity FSH 1200 IU and luteinizing hormone activity LH 1200 IU.

After reconstitution, 1 ml of the reconstituted solution contains 600 IU of highly purified menotrophin.

Human Chorionic Gonadotrophin (hCG), a naturally occurring hormone in postmenopausal urine, is present in MENOPUR and is the main contributor of the LH activity.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder and solvent for solution for injection.

Product imported from the Czech Republic and Greece:

Appearance of powder: white to off-white lyophilisation cake

Appearance of solvent: clear colourless solution.

4 CLINICAL PARTICULARS

As per PA1009/015/003

5 PHARMACOLOGICAL PROPERTIES

As per PA1009/015/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Powder

Lactose monohydrate

Polysorbate 20

Sodium phosphate dibasic heptahydrate (for pH adjustment)

Phosphoric acid (concentrated) (for pH adjustment)

Solvent

Metacresol

Water for Injections

6.2 Incompatibilities

MENOPUR should not be administered in the same injection with other products.

6.3 Shelf life

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

After reconstitution, the solution may be stored for a maximum of 28 days at not more than 25 °C. Do not freeze.

The patient should write the date of first preparation of MENOPUR on the outer carton.

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C). Do not freeze.

For storage conditions after reconstitution of the medicinal product, see SmPC section 6.3 of PA1009/015/003.

6.5 Nature and contents of container

Powder: 2 ml colourless glass vial with rubber stopper closed with a cap.

Solvent: 1 ml pre-filled syringe with rubber tip cap and plunger rubber stopper.

The product is supplied as a pack of 1 vial of powder, 2 pre-filled syringes with solvent for reconstitution, 1 needle for reconstitution, and 18 disposable syringes for administration graduated in FSH/LH units with pre-fixed needles.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

The powder should only be reconstituted with the solvent provided in the package.

Attach the reconstitution needle to the prefilled syringe. MENOPUR 1200 IU must be reconstituted with two pre-filled syringes with solvent before use.

The powder should dissolve quickly to a clear solution. If not, roll the vial gently between the hands until the solution is clear. Shaking should be avoided.

The single use administration syringes with pre-fixed needle are graduated in FSH/LH units from 37.5 – 600 IU.

Draw up the reconstituted solution from the vial into the administration syringe for injection according to the prescribed dose and administer the dose immediately. Each ml of reconstituted solution contains 600 IU FSH and LH.

Each reconstituted MENOPUR 1200 IU vial should be for individual patient use only.

The reconstituted solution should not be administered if it contains particles or is not clear.
Any unused 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

PPA0465/453/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27th May 2022

10 DATE OF REVISION OF THE TEXT