Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

MENOPUR 600 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 600IU and luteinizing hormone activity LH 600IU.

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 the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder and solvent for solution for injection

Product imported from Greece

Appearance of powder: white to off-white lyophilisation cake
Appearance of solvent: clear colourless solution

4 CLINICAL PARTICULARS

As per PA1009/015/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1009/015/002

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 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.

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 section 6.3.

6.5 Nature and contents of container

Powder: colourless vial with rubber stopper closed with a cap.

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

The product is supplied as a pack of 1 vial of powder, 1 pre-filled syringe with solvent for reconstitution, 1 needle for reconstitution and 9 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 600 IU must be reconstituted with one pre-filled syringe 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 600 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

PPA0465/453/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th June 2020

10 DATE OF REVISION OF THE TEXT