Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

PROSTAP 3 DCS 11.25 mg Powder and Solvent for Prolonged-release Suspension for Injection in Pre-filled Syringe

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Powder: Each single-dose syringe contains 11.25 mg leuprorelin acetate.

When reconstituted with Sterile Solvent, the suspension contains 11.25 mg leuprorelin acetate.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Powder and solvent for prolonged–release suspension for injection in pre-filled syringe (Dual Chamber Syringe).

Powder: A sterile, lyophilised, white, odourless powder.
Solvent: A colourless, odourless, slightly viscous, aqueous sterile solvent.

4 CLINICAL PARTICULARS

As per PA2229/009/001

5 PHARMACOLOGICAL PROPERTIES

As per PA2229/009/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Powder
Poly (D-L lactic acid)
Mannitol (E421)

Solvent
Carmellose Sodium
Mannitol (E421)
Polysorbate 80
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 blister and outer package of the product on the market in the country of origin.

Once re-constituted with sterile solvent, the suspension should be administered immediately.

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate or freeze. Store in the original package to protect from light.

6.5 Nature and contents of container

One dual chamber pre-filled syringe containing 11.25mg leuprorelin acetate in the front chamber and 1 ml of aqueous sterile solvent in the rear chamber.

1 x 23 gauge syringe needle fitted with safety device
1 x syringe plunger

6.6 Special precautions for disposal and other handling

Prepare the injectable suspension at the time of use and, after reconstituting, use immediately. Always ensure the safety device to prevent needle-stick injury is deployed after injection. For single use only. Discard any unused content. 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

PPA0465/473/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th December 2021

10 DATE OF REVISION OF THE TEXT