Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sandostatin LAR 20 mg powder and solvent for suspension for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One vial contains 20 mg octreotide (as octreotide acetate)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder and solvent for suspension for injection.

Product imported from Austria:
Powder: White to white with yellowish tint.
Solvent: Clear, colourless to slightly yellow or brown solution.

4 CLINICAL PARTICULARS

As per PA0896/028/005

5 PHARMACOLOGICAL PROPERTIES

As per PA0896/028/005

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Powder (Vial):
Poly(DL-lactide-co-glycolide)
Mannitol (E421)

Solvent (Prefilled syringe):
Carmellose sodium
Mannitol (E421)
Poloxamer 188
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 for this product shall be the date shown on the packaging of the product on the market in the country of origin.
The product must not be stored after reconstitution (must be used immediately).

6.4 Special precautions for storage

Store in the original package in order to protect from light.
Store in a refrigerator (2°C to 8°C). Do not freeze.
Sandostatin LAR may be stored below 25°C on the day of the injection.

For storage conditions after reconstitution, refer to section 6.3.

6.5 Nature and contents of container

Unit packs containing one 6 mL glass vial with rubber stopper (bromobutyl rubber), sealed with an aluminium flip-off seal, containing powder for suspension for injection and one 3 mL colourless pre-filled glass syringe with front and plunger stopper (chlorobutyl rubber) with 2 mL solvent, co-packaged in a sealed blister tray with one vial adapter and one safety injection needle.

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

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
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Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/514/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th March 2025

10 DATE OF REVISION OF THE TEXT