Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Somatuline Autogel 120 mg, solution for injection in a pre-filled syringe

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pre-filled syringe contains a supersaturated solution of lanreotide acetate corresponding to 0.246 mg of lanreotide base/mg of solution, which ensures an actual injection dose of 120 mg of lanreotide.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection in a pre-filled syringe.

Product imported from Belgium, the Czech Republic and Norway:

White to pale yellow semi solid formulation.

4 CLINICAL PARTICULARS

As per PA0869/004/004

5 PHARMACOLOGICAL PROPERTIES

As per PA0869/004/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections
Glacial acetic acid (for pH adjustment)

6.2 Incompatibilities

Not applicable.

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 opening the protective laminated pouch, the product should be administered immediately.

6.4 Special precautions for storage

Store in refrigerator between (2°C to 8°C). Store in the original package in order to protect from light.

Once removed from the refrigerator, product left in its sealed pouch may be returned to the refrigerator for continued storage and later use, provided it has been stored for no longer than 72 hours at below 40°C and the number of temperature excursions does not exceed three.

6.5 Nature and contents of container

Somatuline Autogel is supplied in a pre-filled syringe (clear polypropylene) fitted with an automatic safety system, a needle (stainless steel), a plastic needle sheath (LDPE) and a plunger stopper (bromobutyl rubber).

Each pre-filled syringe is packed in a laminated pouch (polyethylene teraphtalate/aluminium /polyethylene laminate) and a cardboard box.

Box of one 0.5 ml pre-filled syringe with an automatic safety system and one needle (1.2 mm x 20mm).

6.6 Special precautions for disposal and other handling

The solution for injection in a pre-filled syringe is ready for use.
For immediate and single use following first opening.
It is important that the injection of the product is performed exactly according to the instructions in the package leaflet.
Do not use if the laminated pouch is damaged or opened.
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

PPA0465/478/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th September 2021

10 DATE OF REVISION OF THE TEXT

January 2026