

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Somatuline Autogel 60 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 60 mg of lanreotide.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection in a pre-filled syringe.

Product imported from Italy.

White to pale yellow semi solid formulation.

4 CLINICAL PARTICULARS

As per PA0869/004/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0869/004/002

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 for this product shall be the date shown on the pouch, syringe 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) in the original package.

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 24 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 (polypropylene) fitted with an automatic safety system with a plunger stopper (bromobutyl rubber) and a needle (stainless steel) covered by a plastic cap.

Each ready to use pre-filled syringe is placed into a plastic tray and packed in a laminated pouch and a cardboard box. Box of one 0.5 ml pre-filled syringe with an attached needle (1.2 mm x 20 mm).

6.6 Special precautions for disposal

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

Originalis B.V.,
Joop Geesinkweg 901,
1114 AB Amsterdam-Duivendrecht,
Netherlands

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/026/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th February 2023

10 DATE OF REVISION OF THE TEXT