

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Saizen 8 mg/ml solution for injection in cartridge

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each cartridge contains 1.50 ml solution (12 mg somatropin*)

* recombinant human growth hormone, produced by recombinant DNA technology in mammalian cells

One ml of solution contains 8 mg somatropin.

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection in cartridge.

Product imported from Czech Republic:

Clear to slightly opalescent solution with pH of 5.6-6.6 and osmolality 250-450 mOsm/kg.

4 CLINICAL PARTICULARS

As per PA2286/006/002

5 PHARMACOLOGICAL PROPERTIES

As per PA2286/006/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Poloxamer 188
Phenol
Citric acid (for pH adjustment)
Sodium hydroxide (for pH adjustment)
Water for injection

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 is the date shown on the container and outer carton of the product as marketed in the country of origin.

Chemical, physical and microbiological in use stability has been demonstrated for a total of 28 days at 2°C to 8°C, of which up to 7 days can be at or below 25°C.

Other in-use storage times and conditions are the responsibility of the user.

6.4 Special precautions for storage

Store the unused Saizen cartridge in a refrigerator (2°C-8°C). Do not freeze. Store in the original package to protect from light. After first injection, the Saizen cartridge, the easypod auto-injector containing the Saizen cartridge or the aluetta pen injector containing the Saizen cartridge has to be stored in a refrigerator (2°C-8°C) for a maximum of 28 days, of which up to 7 days can be outside of a refrigerator at or below 25°C (see section 6.4. of SmPC of PA2286/006/002). When stored outside of the refrigerator for up to 7 days, the Saizen cartridge must be returned to the refrigerator and used within 28 days after first injection.

When using the easypod auto-injector or the aluetta pen injector, the cartridge is kept in the device.

6.5 Nature and contents of container

The container is a colourless type I glass cartridge with closure consisting of a bromobutyl rubber plunger stopper and an aluminium crimp cap with a bromobutyl rubber single inlay. The glass cartridge containing 12 mg somatropin is marked with a coloured label (red). The glass cartridge containing 20 mg somatropin is marked with a coloured label (yellow).

Saizen 8 mg/ml solution for injection in cartridge is available in pack of 1 cartridge containing 1.50 ml solution (12 mg somatropin).

6.6 Special precautions for disposal and other handling

The cartridge containing the solution of Saizen 8 mg/ml is for use only with the easypod auto-injector or the aluetta pen injectors.

The aluetta pen injectors and Saizen cartridges are available in several presentations. Each aluetta pen injector is colour coded and must only be used with the matching colour coded Saizen cartridge to give the correct dose. The aluetta pen injector 12 (red) must be used with the cartridge containing 12 mg somatropin (red). The aluetta pen injector 20 (yellow) must be used with the cartridge containing 20 mg somatropin (yellow).

For storage of injectors containing a cartridge, see section 6.4. of SmPC of PA2286/006/002.

The solution for injection should be clear to slightly opalescent with no particles and without visible signs of deterioration. If the solution contains particles, it must not be injected.

Any unused medicinal 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

PPA0465/506/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st June 2024

10 DATE OF REVISION OF THE TEXT