Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Norditropin NordiFlex 10 mg/1.5 ml solution for injection in pre-filled pen

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Norditropin NordiFlex: 10 mg/1.5 ml
One ml of solution contains 6.7 mg somatropin
Somatropin (recombinant DNA origin produced in E-coli)
1 mg of somatropin corresponds to 3 IU (International Unit) of somatropin.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection in pre-filled pen

Product imported from Lithuania
Clear, colourless solution.

4 CLINICAL PARTICULARS

As per PA0218/040/009

5 PHARMACOLOGICAL PROPERTIES

As per PA0218/040/009

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol
Histidine
Poloxamer 188
Phenol
Water for injection
Hydrochloric acid for pH adjustment
Sodium hydroxide for pH adjustment

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 pre-filled pen and outer package of the product on the market in the country of origin.

After first opening: Store for a maximum of 4 weeks in a refrigerator (2 °C – 8 °C).
Alternatively, the medicinal product may be stored for a maximum of 3 weeks below 25 °C.

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C) in the outer carton, in order to protect it from light. Do not freeze. Do not store close to any cooling elements. For storage conditions after first opening of the medicinal product, see section 6.3.

When in use, always replace the pen cap on the Norditropin NordiFlex pre-filled pen after each injection. Always use a new needle for each injection.
The needle must not be screwed onto the pre-filled pen when it is not in use.

6.5 Nature and contents of container

Norditropin NordiFlex 10 mg/1.5 ml is a multidose disposable pre-filled pen, which consists of a cartridge (Type I colourless glass) permanently sealed in a plastic pen-injector. The cartridge is closed at the bottom with a rubber stopper (Type I rubber closures) shaped as a plunger and at the top with a laminated rubber stopper (Type I rubber closures) shaped as a disc and sealed with an aluminium cap. The push button on the pen-injector is coloured blue. Pack sizes of 1 pre-filled pen.
The pre-filled pen is packed in a carton.

6.6 Special precautions for disposal and other handling

Norditropin NordiFlex is a pre-filled pen designed to be used with NovoFine or NovoTwist disposable needles up to a length of 8 mm.
Norditropin NordiFlex 10 mg/1.5 ml delivers a maximum of 3.0 mg somatropin per dose, in increments of 0.050 mg somatropin.

To ensure proper dosing and avoid injection of air, check the growth hormone flow before the first injection. Do not use Norditropin NordiFlex if a drop of growth hormone does not appear at the needle tip. A dose is selected by turning the dose selector, until the desired dose appears at the window of the housing. If the wrong dose is selected, the dose can be corrected by turning the dosage selector the opposite way. The push button is pressed to inject the dose.

Norditropin NordiFlex should not be shaken vigorously at any time.

Do not use Norditropin NordiFlex if the growth hormone solution for injection is cloudy or discoloured. Check this by turning the pen upside down once or twice.

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

PPA0465/484/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th January 2022

10 DATE OF REVISION OF THE TEXT

July 2022