Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Decapeptyl 3-month, 11.25 mg Powder and solvent for suspension for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains the quantity of triptorelin (as triptorelin pamoate) to ensure that the minimum triptorelin quantity injected is 11.25 mg.

Excipients:
Sodium < 1 mmol (23 mg)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Product imported from Poland and Romania:
Powder for suspension for injection:
Sightly yellow lyophilised cake.

Solvent for suspension for injection:
Clear, colourless solution free of suspended particles.

4 CLINICAL PARTICULARS

As per PA0869/003/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0869/003/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

D,L lactide coglycolide polymers
Mannitol
Sodium carmellose
Polysorbate 80
Water for injections

6.2 Incompatibilities

Not applicable. The product is not intended for admixture.

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 on the market in the country of origin.

The product should be used immediately after reconstitution. Any remaining product should be discarded.

6.4 Special precautions for storage

Store below 25 °C in the original package.

6.5 Nature and contents of container

Powder for suspension for injection:
Clear slightly tinted glass vial (4ml)

Solvent for suspension for injection:
Clear glass ampoule (2ml)

Box containing 1 vial and 1 ampoule with 1 syringe 3 needles. The injection needle is equipped with a safety shield.

6.6 Special precautions for disposal and other handling

The suspension for injection must be reconstituted using an aseptic technique and only using the ampoule of solvent for injection. The instructions for reconstitution hereafter and in the leaflet must be strictly followed. The solvent should be drawn into the syringe provided using the reconstitution needle (20 G, without safety device) and transferred to the vial containing the powder. The suspension should be reconstituted by swirling the vial gently from side to side for long enough until a homogeneous, milky suspension is formed. Do not invert the vial. It is important to check there is no unsuspended powder in the vial. The suspension obtained should then be drawn back into the syringe, without inverting the vial. The reconstitution needle should then be changed and the suspension should be injected immediately using the specific injection needle:

- The 38 mm length needle (20 G) with safety device for intramuscular injection in the gluteal muscle (patients treated for prostate cancer, endometriosis or central precocious puberty)

- The 25 mm length needle (20 G) with safety device for subcutaneous injection in abdomen or thigh (only patients treated for prostate cancer). As the product is a suspension, the injection should be administered immediately after reconstitution to prevent precipitation. For single use only.

Used needles, any unused suspension or other waste materials should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/126/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th September 2019

10 DATE OF REVISION OF THE TEXT

November 2023