Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Decapeptyl 6-month 22.5 mg Powder and solvent for prolonged-release suspension for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains triptorelin pamoate equivalent to 22.5 mg triptorelin.

After reconstitution in 2 mL solvent, 1 mL of reconstituted suspension contains 11.25 mg of triptorelin. Contains sodium but less than 1mmol (23 mg) sodium per vial.

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Powder and solvent for prolonged-release suspension for injection

Product imported from Belgium and Czech Republic:
Powder: White to off-white powder.
Solvent: Clear solution.

4 CLINICAL PARTICULARS

As per PA0869/003/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0869/003/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from Belgium:
Powder:
Poly (d,l-lactide-co-glycolide)
Mannitol
Carmellose sodium
Polysorbate 80

Solvent:
Water for injections

Product imported from Czech Republic:
Powder:
Polyglactin
Mannitol
Carmellose sodium
Polysorbate 80

Solvent:
Water for injections

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 container and outer package of the product on the market in the country of origin.

Use immediately after reconstitution.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Vial with stopper and flip-off cap.

Ampoule containing 2 mL of sterile solvent for suspension.

Box of:
1 vial, 1 ampoule and 1 blister containing 1 injection syringe and 2 injection needles.

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 injection needle (20 G, with safety device) used to administer the product.
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 medicinal product or suspension or other waste materials should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
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Ballycoolin
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Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/126/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd July 2021

10 DATE OF REVISION OF THE TEXT

November 2023