

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zoladex 3.6 mg implant

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Goserelin acetate equivalent to 3.6 mg goserelin.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Implant.

Product imported from Romania:

Implant in a pre-filled syringe.

4 CLINICAL PARTICULARS

As per PA1019/027/001

4.1 Therapeutic Indications

5 PHARMACOLOGICAL PROPERTIES

As per PA1019/027/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactide/glycolide copolymer.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original container.

6.5 Nature and contents of container

Zoladex 3.6 mg Implant is supplied as a single dose SafeSystem™ syringe applicator with a protective sleeve in a sealed pouch which contains a desiccant.

6.6 Special precautions for disposal and other handling

Use as directed by the prescriber. Use only if pouch is undamaged. Use immediately after opening pouch.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
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Ballycoolin
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Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/125/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th June 2019

10 DATE OF REVISION OF THE TEXT