

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Zoladex LA 10.8 mg implant

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Goserelin acetate equivalent to 10.8 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 PA1019/027/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1019/027/002

## 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 carton of the product as marketed 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 LA is supplied as a single dose Safe System™ 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.  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/125/002

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 14<sup>th</sup> June 2019

**10 DATE OF REVISION OF THE TEXT**