

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Zoladex LA 10.8 mg Implant

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each implant contains 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 and Greece.*

Cylindrical 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 copolymers.

### 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

To be stored at a temperature lower than 25°C. Do not freeze. To be stored in the original packaging.

### 6.5 Nature and contents of container

Zoladex LA comes in the form of an implant in a ready-to-use pre-filled syringe. It 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

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

**7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Originalis B.V.,  
Joop Geesinkweg 901,  
1114 AB Amsterdam-Duivendrecht,  
Netherlands

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA2306/027/001

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

Date of first authorisation: 23<sup>rd</sup> June 2023

**10 DATE OF REVISION OF THE TEXT**