Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zoladex LA 10.8mg Implant

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Goserelin acetate equivalent to 10.8mg goserelin
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Implant
Product imported from Poland and Romania
A white to cream-coloured, cylindrical depot in a pre-filled syringe

4 CLINICAL PARTICULARS

As per PA 0970/025/002.

5 PHARMACOLOGICAL PROPERTIES

As per PA 0970/025/002.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactide/glycolide 95/5 copolymer Low Molecular Weight
Lactide/glycolide 95/5 copolymer High Molecular Weight

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 packaging of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C. Keep in its original packaging and do not break the seal.

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.
Over-labelled cardboard carton containing one implant
Pack size: 1 applicator containing 1 implant

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

Imbat Ltd
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/133/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th January 2010

10 DATE OF REVISION OF THE TEXT

October 2015