

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mirena 52 mg Intrauterine Delivery System

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Levonorgestrel 52 mg.

The in-vivo dissolution rate is about 20 microgram/24 hours initially and is reduced to about 10 microgram/24 hours after five years.

The mean dissolution rate of levonorgestrel is about 15 micogram/24 hours over the time up to five years.

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Intrauterine delivery system.

Product imported from Greece, France and Spain

The levonorgestrel intrauterine delivery system consists of a white or almost white drug core covered with an opaque membrane, which is mounted on the vertical stem of a T-body. The T-body has a loop at one end of the vertical stem and two horizontal arms at the other end. Removal threads are attached to the loop. The vertical stem of the intrauterine delivery system is loaded in the insertion tube at the tip of the inserter.

4 CLINICAL PARTICULARS

As per PA1410/008/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1410/008/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from Greece and France:

Polydimethylsiloxane elastomer

Polydimethylsiloxane tubing

Polyethylene

Barium sulphate

Iron oxide

Product imported from Spain:

Polydimethylsiloxane elastomer

Colloidal silica anhydrous

Polyethylene

Barium sulphate

Iron oxide

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

6.4 Special precautions for storage

Product imported from Greece:

Do not store above 30°C. Store in the original package to protect from moisture and direct sunlight.

Product imported from France and Spain:

Store in the original package to protect from moisture and direct sunlight.

6.5 Nature and contents of container

The product is individually packed into a thermoformed blister package with a peelable lid.

6.6 Special precautions for disposal and other handling

Mirena is supplied in a sterile pack which should not be opened until required for insertion. The exposed product should be handled with aseptic precautions. If the seam of the sterile envelope is broken, the product inside should be discarded. Special instructions for insertion are in the package. For further information see also Section 4.2, Posology and Method of Administration, Insertion and removal/replacement.

Any unused product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
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Rath
Ashbourne
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/292/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th August 2012

10 DATE OF REVISION OF THE TEXT

March 2023