Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Kyleena 19.5 mg intrauterine delivery system

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The intrauterine delivery system contains 19.5 mg levonorgestrel.

For details of release rates, see section 5.2. of PA1410/081/001 SmPC.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Intrauterine delivery system (IUS).

Product imported from Norway:
The product consists of a white or almost white drug core covered with a semi-opaque membrane, which is mounted on the vertical stem of a T-body. In addition, the vertical stem contains a silver ring located close to the horizontal arms. The white T-body has a loop at one end of the vertical stem and two horizontal arms at the other end. The blue coloured removal threads are attached to the loop. The vertical stem of the IUS is loaded in the insertion tube at the tip of the inserter. The inserter consists of a handle and slider that are integrated with flange, lock, pre-bent insertion tube and plunger. The removal threads are located within the insertion tube and handle.

Dimensions of Kyleena: 28 x 30 x 1.55 mm

4 CLINICAL PARTICULARS

As per PA1410/081/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1410/081/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polydimethylsiloxane elastomer
Silica, colloidal anhydrous
Polyethylene
Barium sulfate
Polypropylene
Copper phthalocyanine
Silver

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

The product is individually packed into a thermoformed blister package (PETG) with a peelable lid (PE).
Pack size: 1x1.

6.6 Special precautions for disposal

The product is supplied in a sterile package which should not be opened until required for insertion. Each system should be handled with aseptic precautions. If the seal of the sterile envelope is broken, the system inside should be disposed of in accordance with local guidelines for the handling of biohazardous waste. Likewise, a removed Kyleena and inserter should be disposed of in this manner.

To be inserted by a healthcare professional using aseptic technique (see section 4.2 of PA1410/081/001 SmPC).

Any unused medicinal product or waste material should be disposed of in accordance with local requirements. This medicinal product may pose a risk to the environment (see section 5.3 of PA1410/081/001 SmPC).

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
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Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/516/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th July 2025

10 DATE OF REVISION OF THE TEXT