

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lubion 25 mg solution for injection in pre-filled syringe

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pre-filled syringe (1.112 ml) contains 25 mg of progesterone (22.48 mg/ml).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection

Product imported from Italy:

Clear colourless solution, essentially free from visible particles.

4 CLINICAL PARTICULARS

As per PA1104/006/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1104/006/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydroxypropylbetadex
Disodium phosphate
Sodium dihydrogen phosphate dihydrate
Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the syringe and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not refrigerate or freeze.

Store in the original package in order to protect from light.

6.5 Nature and contents of container

Lubion is supplied in a glass pre-filled syringe with a mounted needle and needle cover.

Each carton contains 7 pre-filled syringes.

6.6 Special precautions for disposal and other handling

The solution is for single-use only.

The solution should not be administered if it contains particles or is discoloured.

This medicinal product may pose a risk to the environment (see section 5.3 of SmPC PA1104/006/001).

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/524/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th June 2026

10 DATE OF REVISION OF THE TEXT