

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Crinone 8% w/w progesterone vaginal gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient	Mg/dose	% w/w
Progesterone	90	8.0

Excipients: Contains sorbic acid

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Vaginal gel

Product imported from the Romania

White to off white gel contained in a white plastic applicator.

4 CLINICAL PARTICULARS

As per PA2286/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA2286/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Light liquid paraffin
Hydrogenated palm oil glycerides
Carbomer 974P
Sorbic acid
Polycarbophil
Sodium hydroxide
Purified water

6.2 Incompatibilities

No incompatibilities were found with the usual contraceptive devices.

6.3 Shelf life

The shelf life expiry date for this product shall be 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

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

6.5 Nature and contents of container

A single use, one piece, white polyethylene applicator with a twist-off top, designed for intravaginal application.

Each applicator contains 1.45g of gel and delivers 1.125g of gel. Each one is wrapped up and sealed in a paper/aluminium/polyethylene foil overwrap.

The applicators are packed in cardboard boxes containing 15 units of Crinone 8% progesterone vaginal gel.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon Pharmaceuticals (Ireland) Limited
Block 3
Harcourt Centre
Harcourt Road
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/031/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th July 2020

10 DATE OF REVISION OF THE TEXT

February 2022