

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 Czech Republic, Greece, Italy, Bulgaria and 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

Glycerin
Liquid Paraffin
Hydrogenated Palm Oil Glycerides
Carbomer 974P
Sorbic acid (E200)
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 of 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

Do not store above 25°C.

Do not Freeze.

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 applicator is individually sealed.

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

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/301/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22nd February 2013

10 DATE OF REVISION OF THE TEXT

January 2023