

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Crinone 8% w/w progesterone vaginal gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient

Progesterone	Mg/dose	% w/w
	90	8.0

Excipients: Contains sorbic acid

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Vaginal gel

Product imported from Greece, Italy and Romania:

White to off white gel contained in a 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
Light 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 is the date shown on the container and outer carton 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, 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

IMED Healthcare Ltd.,
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/112/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st March 2017

10 DATE OF REVISION OF THE TEXT

September 2026