

# 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 0.08% w/w (0.9mg/1.125g dose)

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Vaginal gel

*Product imported from Greece*

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  
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: 31<sup>st</sup> March 2017

### **10 DATE OF REVISION OF THE TEXT**

March 2023