

# 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 UK & Czech Republic:*

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

## 4 CLINICAL PARTICULARS

As per PA0654/021/001.

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0654/021/001.

## 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 shall be the date shown on the foil overwraps and outer carton of the product as marked 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**

Cardboard outer containing single use, one piece applicators in foil overwraps.  
Pack size: 15 applicators

#### **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**

Imbat Ltd  
Unit L2  
North Ring Business Park  
Santry  
Dublin 9  
Ireland

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/235/001

### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 15<sup>th</sup> August 2014

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

January 2016