

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Crinone 4% w/w progesterone vaginal gel

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active Ingredient</u>	<u>4% gel</u>	
	Mg/dose	% w/w
Progesterone	45	4.0

For excipients see section 6.1.

#### 3 PHARMACEUTICAL FORM

Vaginal gel

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

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

Menopausal disposal (in combination with oestrogen therapy).

##### 4.2 Posology and method of administration

###### **Intravaginal application.**

Treatment of menopausal disorders:

One application (1.125g 4% gel) every other day for the last 12 days of each oestrogenic sequence.

Children: not applicable.

##### 4.3 Contraindications

Crinone should not be used in individuals with any of the following conditions:

1. Known sensitivity to Crinone (progesterone or any of the other ingredients).
2. Undiagnosed vaginal bleeding.
3. Known or suspected malignancy of the breast or genital organs.
4. Acute porphyria.
5. Thrombophlebitis, thromboembolic disorder, cerebral apoplexy, or patients with a history of these conditions.

##### 4.4 Special warnings and precautions for use

Crinone 4% Progesterone Vaginal Gel can be prescribed with an oestrogen product as HRT. Epidemiological evidence suggests that the use of HRT is associated with an increased risk of developing deep vein thrombosis (DVT) or pulmonary embolism. The use of Crinone in combination with oestrogen therapy as HRT was not included in these

studies.

However, when Crinone is co-prescribed as HRT the prescribing information for the oestrogen product should be referred to.

In cases of breakthrough bleeding, as in all cases of irregular vaginal bleeding, non-functional causes should be considered. In cases of undiagnosed vaginal bleeding, adequate diagnostic measures should be undertaken.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

Although no interaction with other drugs have been reported. Crinone is not recommended for use with other vaginal preparations.

#### **4.6 Pregnancy and lactation**

Not applicable.

#### **4.7 Effects on ability to drive and use machines**

Drivers and users of machines are warned that risk of somnolence may occur.

#### **4.8 Undesirable effects**

Headache, somnolence, breast tenderness, intermenstrual bleeding (spotting), vaginal irritation and other mild application site reactions.

#### **4.9 Overdose**

Not applicable.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Those of the naturally occurring progesterone with induction of a full secretory endometrium.

#### **5.2 Pharmacokinetic properties**

The progesterone vaginal gel is based on a polycarbophil delivery system which attaches to the vaginal mucosa and provides a prolonged release of progesterone for at least three days.

#### **5.3 Preclinical safety data**

In rabbits, Crinone was an eye irritant categorised class IV (minimal effects clearing in less than 24 hours), but not a dermal irritant.

### **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**

3 years.

## **6.4 Special precautions for storage**

Do not store above 25°C.

## **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 2.6g of gel and delivers 1.125 of gel. Each one is wrapped up and sealed in a paper/aluminium/polyethylene foil overwrap.

The applicators are packed in cardboard boxes containing 6 units of Crinone 4% 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**

None.

## **7 MARKETING AUTHORISATION HOLDER**

Serono Limited  
Bedfont Cross  
Stanwell Road  
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## **8 MARKETING AUTHORISATION NUMBER**

PA 285/13/1

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

Date of first authorisation: 25 July 1997

Date of last renewal: 25 July 2002

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

May 2004