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

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

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

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Infertility due to inadequate luteal phase.

4.2 Posology and method of administration

Posology
Intravaginal application.

Treatment of infertility due to inadequate luteal phase:
One application (1.125g 8% gel) every day, starting after documented ovulation or arbitrarily on the 18th-21st day of the cycle.

Paediatric population
Not applicable.

4.3 Contraindications

Crinone should not be used in individuals with any of the following conditions:
1. Hypersensitivity to the active substance or to any of the other excipients listed in section 6.1.
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.
6. Missed abortion.

4.4 Special warnings and precautions for use

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.

Sorbic acid may cause local skin reactions, (e.g. contact dermatitis).

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 concurrently with other vaginal preparations.

4.6 Fertility, pregnancy and lactation

Breast-feeding
Do not use during lactation.

Pregnancy
In case of corpus luteum deficiency, Crinone can be used during the first month of pregnancy.

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

System Organ Class	**Common**
Nervous system disorders	Headache
Reproductive system and breast disorders	Breast tenderness.
Psychiatric disorders	Somnolence

For adverse reactions identified during post-marketing surveillance, the frequency is not known.
In addition, intermenstrual bleeding (spotting), vaginal irritation, hypersensitivity reactions usually manifesting as skin rash, and other mild application site reactions have been reported post-marketing.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via
HPRA Pharmacovigilance
Website: www.hpra.ie

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Sex hormones, ATC code: G03DA04

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.

A moderate vaginal irritation was found in rabbits after application of 2.0ml/day of 8% gel for 5 days.

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 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 6 units of Crinone 8% progesterone vaginal gel, and 15 units of Crinone 8% progesterone vaginal gel.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Merck Serono (Ireland) Limited
4045 Kingswood Road
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA2286/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25 July 1997

Date of last renewal: 25 July 2007

10 DATE OF REVISION OF THE TEXT

June 2022