SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Crinone 8% vaginal gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose contains: progesterone 90 mg

Excipient with known effect
Sorbic acid 0.9 mg.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Vaginal gel

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Luteal phase support to women, down regulated with GnRH-agonists during ovulation induction with gonadotropins.

4.2 Posology and method of administration

Vaginal use

Luteal phase support
90 mg progesterone (one applicator) each day, beginning the day of ovulation or the same day as the *in vitro* fertilisation takes place. The most suitable duration for the treatment has not been studied.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Undiagnosed vaginal bleeding.
Acute porphyria. Malignancy of the breast or genital organs.
Thromboembolic disease, stroke, or patients with a history of these conditions.

4.4 Special warnings and precautions for use

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

Take caution for patients with severe liver insufficiency.

Pregnancy should be monitored during treatment with Crinone.

In case of missed abortion the treatment should be discontinued.

The preservative sorbic acid may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

Crinone is not recommended for use concurrently with other vaginal preparations.

4.6 Fertility, pregnancy and lactation

Pregnancy
In case of corpus luteum deficiency, Crinone can be used during the first trimester. A large amount of data on pregnant women (more than 1000 exposed outcomes) indicate no association between the maternal use of natural progesterone in early pregnancy and foetal malformations.

Breast-feeding
Crinone should not be used during lactation.

Fertility
Crinone is indicated for the use of progesterone supplementation of the luteal phase in adults as part of an ART (assisted reproductive technology) procedure (see section 4.1).

4.7 Effects on ability to drive and use machines

Crinone has no known influence on the ability to drive and use machines.

4.8 Undesirable effects

Common (≥1/100, <1/10)
Reproductive system and breast disorders: Breast tenderness, vaginal discharge
General disorders and administration site conditions: Headache, somnolence

Frequency not known (cannot be estimated from the available data)
Reproductive system and breast disorders: Intermenstrual bleeding (spotting)
General disorders and administration site conditions: Vaginal irritation at the application site
Skin and subcutaneous tissue disorders: Hypersensitivity reactions usually manifesting as skin rash

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 the national reporting system listed in Appendix V.

4.9 Overdose

No known cases of an overdose of Crinone.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Gestagenes
ATC code: G03DA04

The pharmacological effect is the same as for natural progesterone. If luteal phase support with Crinone will improve the pregnancy rate in women with functioning ovaries compared to untreated women, have not been studied.

5.2 Pharmacokinetic properties

The progesterone vaginal gel is based on a polycarbophilic releasing system. The system facilitates attachment to the vaginal mucous membrane and a delivery of progesterone during at least 3 days. Vaginal administration of progesterone will give considerably higher local endometric concentrations compared to a normal luteal phase.

5.3 Preclinical safety data

No other preclinical data, except those presented in other sections in this Summary of Product Characteristics, are available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol, light liquid paraffin, hydrogenated palm oil glycerides, carbomer, polycarbophil, sorbic acid (E 200, preservative), sodium hydroxide, purified water

6.2 Incompatibilities

Not relevant.

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 white polyethylene applicator, with a top that can be twisted-off. Each applicator contains 1.45 g gel and delivers 1.125 g gel. Each applicator is wrapped up and sealed in a paper / aluminium / polyethylene foil overwrap.
The applicators are packed in a paper box with 6 or 15 applicators of Crinone 8% vaginal gel.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

[To be completed nationally]

8. MARKETING AUTHORISATION NUMBER

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

2021-06-17

[To be completed nationally]