Info-Table - Version 03

IDENTIFICATION OF THE COMPONENT	
Material component code:	40405560004
Local brand:	CRINONE
Strength(s):	8%
TECHNICAL DATA	
Packaging site:	Catalent Nottingham UK
Technical layout ref:	148x210mm_V03
BARCODE	
Barcode type:	Laetus
Alpha numeric content:	550
Spotmark:	No
Spotmark value:	No

TRACEABILITY (VERSIONS)		
Vx	Date	Designer
01	16.11.2020	Kristine Vitola
02	17.11.2020	Kristine Vitola
03	n/a	n/a

COLOURS	
Printed colour(s)	Technical information(s)
Black	Keyline

DISETUJUI OLEH BPOM : 25/03/2021

Crinone® 8%
Progesterone

1. NAME OF THE MEDICINAL PRODUCT

Crinone 8% Progesterone Vaginal Gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient

	mg/dose	% w/w
Progesterone	90	8.0

3. PHARMACEUTICAL FORM

Vaginal gel

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

- Treatment of infertility due to inadequate luteal phase.
- For use during in-vitro fertilisation, where infertility is mainly due to tubal, idiopathic or endometriosis linked sterility associated with normal ovulatory cycles.

4.2 Posology and Method of Administration

Posology

Intravaginal application

Treatment of infertility due to inadequate luteal phase

One application (1.125 g 8% gel) every day, starting after documented ovulation or arbitrarily on the 18th - 21st day of the cycle.

Use during in-vitro fertilisation

Daily application of Crinone 8% gel should be continued for 30 days if there is laboratory evidence of pregnancy.

Children: Not applicable

The Elderly: Not applicable

Method of Administration

Crinone is applied directly from the specially designed sealed applicator into the vagina. The applicator should be removed from the sealed wrapper. The twist-off cap should not be removed at this time.

1. The applicator should be gripped firmly by the thick end. It should be shaken down like a thermometer to ensure that the contents are at the thin end.
2. The tab should be twisted off and discarded.
3. The applicator may be inserted while patient is in a sitting position or when lying on her back with the knees bent. The thin end of applicator should be gently inserted well into the vagina.
4. The thick end of the applicator should be pressed firmly to deposit gel. The applicator should be removed and discarded in a waste container.

4.3 Contraindications

1. Known hypersensitivity to Progesterone or any of the excipients.
2. Undiagnosed vaginal bleeding.
3. Known or suspected Progesterone-sensitive malignant tumours.
4. Porphyria.

4.4 Special Warnings and Precautions for Use

Cautious use in severe hepatic insufficiency.

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.

Avoid concurrent use with other intravaginal preparations. See Interaction with medicaments and other forms of interactions.

The excipient sorbic acid may cause local skin reactions (e.g. contact dermatitis) or vaginal irritation.

4.5 Interaction with Medicaments and Other Forms of Interactions

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

4.6 Pregnancy and Lactation

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

Do not use during lactation.

4.7 Effects on Ability to Drive and Use Machines

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

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4.8 Undesirable effects

Common (>1/100 – 1/10)

Headache, Somnolence, Breast Tenderness, Vaginal irritation, Itching or Burning

Post Marketing Reports

In addition, intermenstrual bleeding (spotting), hypersensitivity reactions usually manifesting as skin rash, and other mild application site reactions have been reported post-marketing.

Rare events of urticaria and pruritis were noted.

4.9 Overdose

Not applicable

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacological Properties

The pharmacological particulars of the product are 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 2.0 mL/day of 8% gel for 5 days.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Glycerin, Carbomer 974P, Polycarbophil, Hydrogenated Palm Oil Glycerides, Light
Liquid Paraffin, Sorbic Acid, Sodium Hydroxide and Purified Water.

6.2 Incompatibilities

No incompatibilities were found with the usual contraceptive devices.

6.3 Shelf-life

36 months

6.4 Special Precautions for Storage

Store below 30°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 1.45 g of gel and delivers 1.125 g 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 or 15 units of Crinone 8% Progesterone vaginal gel.

HARUS DENGAN RESEP DOKTER

On Medical Prescription Only

Reg. No. DKI1953600152A1

Manufactured by
Dendron Brands Ltd., Watford, UK

Primary packed by
Maropack AG, Zell, Switzerland

Secondary packed by
Central Pharma (Contract Packing) Ltd., Bedford, UK

For
Merck Serono Ltd, Feltham, UK

Imported by
PT Merck Tbk, Jakarta, Indonesia

IP/jt/17Nov2020

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