

CRINONE®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using CRINONE?

CRINONE contains the active ingredient progesterone. CRINONE is used in IVF and ART, where luteal phase support is indicated.

For more information, see Section [1. Why am I using CRINONE?](#) in the full CMI.

2. What should I know before I use CRINONE?

Do not use if you have ever had an allergic reaction to CRINONE or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use CRINONE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CRINONE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use CRINONE?

- CRINONE is applied directly from the applicator deep into the vagina.
- The applicator is designed to deliver a pre-measured dose of progesterone gel. Your doctor will tell you how much CRINONE to use and when to start treatment.

More instructions can be found in Section [4. How do I use CRINONE?](#) in the full CMI.

5. What should I know while using CRINONE?

Things you should do	<ul style="list-style-type: none">• Be sure to keep all your doctor's appointments so your progress can be checked.• Tell any other doctors or pharmacists you
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	<p>visit that you are using CRINONE.</p> <ul style="list-style-type: none"> • If you are about to start taking any new medicines, tell the doctor or pharmacist that you are using CRINONE.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine or change the dose without telling your doctor. • Do not give CRINONE to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none"> • Be careful driving or operating machinery until you know how CRINONE affects you. • Some people feel drowsy and sleepy when using CRINONE. • If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.
Looking after your medicine	<ul style="list-style-type: none"> • Keep CRINONE in a cool place where it stays

below 25°C and is not exposed to extreme heat or cold.

- Do not store CRINONE in a bathroom or near a sink.
- Do not leave it in the car.
- Each applicator must be used once only. Use a new applicator for each treatment.

For more information, see Section [5. What should I know while using CRINONE?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Tell your doctor if you experience any side effects. Most common side effects include cramps, abdominal pain, perineal pain (around the genitals and the back passage), constipation, nausea, headache, breast pain, breast enlargement, feelings of severe sadness and unworthiness, decreased sexual drive, sleepiness, feeling emotional and passing urine at night.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

CRINONE®

Active ingredient: *progesterone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using CRINONE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CRINONE.**

Where to find information in this leaflet:

1. Why am I using CRINONE?
2. What should I know before I use CRINONE?
3. What if I am taking other medicines?
4. How do I use CRINONE?
5. What should I know while using CRINONE?
6. Are there any side effects?
7. Product details

1. Why am I using CRINONE?

CRINONE contains the active ingredient progesterone.

Progesterone is a hormone that is produced by the ovaries during the second half of the menstrual cycle.

It is an essential hormone for preparing the uterus (womb) for pregnancy and on-going support of pregnancy.

CRINONE is used in IVF and ART, where luteal phase support is indicated.

2. What should I know before I use CRINONE?

Warnings

Do not use CRINONE if:

- you have ever had an allergic reaction to progesterone or to any of the ingredients listed at the end of this leaflet

Always check the ingredients to make sure you can use this medicine.

- you have cancer of the breast and genital organs
- you have porphyria
- you have abnormal vaginal bleeding that has not been diagnosed, or is due to a recent or current missed abortion or miscarriage
- you have or have ever had blood clots or stroke
- you have liver disease or abnormal laboratory results

Check with your doctor if you:

- have any other medical conditions (i.e. depression, migraine, epilepsy, asthma, heart, kidney or liver disease)
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

CRINONE is used to support embryo implantation and maintain pregnancies through its use as part of ART treatment.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not use CRINONE if you are breastfeeding.

Talk to your doctor about any concerns you may have before undergoing treatment or before you start using CRINONE.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Do not use Crinone at the same time as other vaginal preparations.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CRINONE.

4. How do I use CRINONE?

How much to use

- The amount of CRINONE used depends on the condition being treated.
- Your doctor may prescribe one applicator of CRINONE either daily or twice daily and will advise you when to start treatment. If pregnancy occurs treatment may continue for up to 12 weeks or as directed by your doctor.
- Follow the instructions provided and use CRINONE until your doctor tells you to stop.

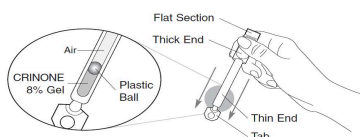
When to use CRINONE

- CRINONE should be used at the same time each day.
- If used twice a day, one applicator of CRINONE should be used in the morning and the other at night.

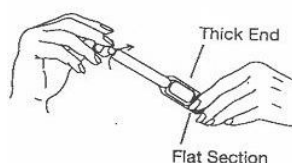
How to use CRINONE

- CRINONE is applied directly from the applicator deep into the vagina to provide a prolonged release of a natural progesterone.

- The applicator is designed to deliver a pre-measured dose of progesterone gel.
- A small amount of gel will be left in the applicator after usage. Do not be concerned because you will still be receiving the required dose.
- Follow all instructions given to you by your doctor or nurse carefully. Follow these steps:
 1. Wash your hands well with soap and water.
 2. Remove the applicator from the sealed wrapper.
 3. **DO NOT REMOVE THE TWIST-OFF TAB AT THIS TIME.**
 4. Hold the applicator by the thick end. Shake down several times like a thermometer to ensure that the contents are at the thin end.
 5. The plastic ball in the thin end helps the gel to move down to the tip of the applicator. The ball also helps to control the release of the gel. The applicator is designed so that the ball cannot exit it.



5. Hold the applicator by the flat section of the thick end. Twist off the tab at the thin end of the applicator and discard it. **DO NOT** squeeze the thick end while twisting off the tab. This may release gel.



6. Carefully insert the applicator into the vagina while you are in a sitting position or when lying on your back with the knees bent. Gently insert the thin end of the applicator well into the vagina.
7. Squeeze the thick end of the applicator firmly to push the gel into the vagina. Remove the applicator and discard into a waste container. There may be some gel left in the applicator. Do not worry; you will still be receiving the correct dose.



CRINONE coats the vaginal lining to provide a prolonged release of progesterone.

If you forget to use CRINONE

CRINONE should be used regularly at the same time each day. If you miss your dose at the usual time, use it as soon as you remember and then continue the same schedule as before.

Do not use more than the recommended daily dose.

If you use too much CRINONE

If you think that you have used too much CRINONE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre

(by calling 13 11 26 in Australia or 0800 764 766 in New Zealand), or

- **contact your doctor, or**
- **go to the Emergency Department at your nearest hospital.**

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using CRINONE?

Things you should do

See your doctor regularly and keep all your doctor's appointments so your progress can be checked.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are using CRINONE.

Remind any doctor, dentist or pharmacist you visit that you are using CRINONE.

Things you should not do

- **Do not stop using this medicine suddenly without telling your doctor.**
- **Do not change the dose unless your doctor tells you to.**
- **Do not give this medicine to anyone else, even if they have the same condition as you.**

Driving or using machines

Be careful before you drive or use any machines or tools until you know how CRINONE affects you.

CRINONE can make some people feel drowsy and sleepy.

If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Looking after your medicine

- Store CRINONE below 25°C.
- Each applicator must be used once only. Use new applicator for each treatment.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
<p>Gastrointestinal system related:</p> <ul style="list-style-type: none">• cramps, bloating, abdominal pain, perineal pain (around the genitals & the back passage)• nausea, constipation• diarrhoea, vomiting <p>Nervous system related:</p> <ul style="list-style-type: none">• headache, dizziness <p>Reproductive system related:</p> <ul style="list-style-type: none">• breast enlargement or breast pain• painful sexual intercourse	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Side effects	What to do
<p>Psychiatric related:</p> <ul style="list-style-type: none"> • feelings of severe sadness and unworthiness, decreased sexual drive, sleepiness, feeling emotional <p>Urine system related:</p> <ul style="list-style-type: none"> • passing urine at night <p>Administration site related:</p> <ul style="list-style-type: none"> • vaginal discharge, itching of vaginal area, vaginal thrush <p>Musculo-skeletal related:</p> <ul style="list-style-type: none"> • painful joints 	

Serious side effects

Serious side effects	What to do
<p>Allergic reactions:</p> <ul style="list-style-type: none"> • swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you</p>

Serious side effects	What to do
difficulty breathing, skin rash, itching or hives	notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems.

In New Zealand, you can report side effects to Medsafe online at <https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What CRINONE contains

Active ingredient (main ingredient)	Progesterone
Other ingredients (inactive ingredients)	Hydrogenated palm glycerides Glycerol Carbomer 974P Sorbic acid Polycarbophil Sodium hydroxide Purified water Light liquid paraffin

Do not take this medicine if you are allergic to any of these ingredients.

What CRINONE looks like

CRINONE is a soft, white to off-white gel. It is supplied in an applicator with a twist-off top. The applicator contains a plastic ball. Each applicator is sealed in a wrapper and contains a single dose of CRINONE.

Each applicator contains 1.45 g of gel and delivers a constant dose of 1.125 g of CRINONE gel containing 90 mg (8% gel) of progesterone.

CRINONE is available in boxes containing 6, 15 or 18 applicators*.

* Not all pack sizes may be available.

Australian Registration Number: AUST R 83166

Who distributes CRINONE

CRINONE is supplied in Australia by:

Merck Healthcare Pty Ltd

Suite 1, Level 1, Building B

11 Talavera Road

Macquarie Park NSW 2113

E-mail: medinfo.australia@merckgroup.com

Phone: 1800 633 463

CRINONE is supplied in New Zealand by:

Healthcare Logistics

58 Richard Pearse Drive

Airport Oaks

Auckland

E-mail: medinfo.australia@merckgroup.com

Phone: 0800 426 252

This leaflet was prepared in August 2025.