

HRT: Progesterone

This leaflet provides important information about using HRT: Progesterone.

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 HRT: Progesterone.

Where to find information in this leaflet:

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

1. WHY AM I USING HRT: PROGESTERONE?

HRT: Progesterone are a compounded bioidentical hormone therapy product that contains the active ingredients Progesterone.

Progesterone is a hormone produced mainly in the ovaries after ovulation and during pregnancy. It plays a critical role in regulating the menstrual cycle and maintaining pregnancy.

In hormone replacement therapy (HRT), progesterone is often used alongside estrogen to treat various symptoms associated with hormonal imbalances, especially during menopause. Common uses include:

- Menstrual Irregularities: Regulates irregular or heavy menstrual bleeding.
- Menopausal Symptoms: Alleviates symptoms such as hot flashes and mood swings when used in combination with estrogen.
- Support for Pregnancy: Helps prepare the uterus for pregnancy and maintains a healthy environment for fetal development.

Progesterone works by binding to progesterone receptors in the uterus and other target tissues.

By restoring progesterone levels, this therapy can:

- Regulate the Menstrual Cycle: Balances the effects of estrogen, helping to establish a regular menstrual cycle.
- Prepare the Uterus for Pregnancy: Prepares the uterine lining for potential implantation of an embryo, supporting early pregnancy.
- Alleviate Menopausal Symptoms: Helps reduce symptoms such as anxiety, mood swings, and sleep disturbances.
- Promote Bone Health: May contribute to maintaining bone density, particularly when used in combination with estrogen.

Your doctor may prescribe HRT: Progesterone for another purpose.

Ask your doctor if you have any questions about why HRT: Progesterone has been prescribed for you.

There is no information on the use of this medicine in those below 18 years of age.

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

2. WHAT SHOULD I KNOW BEFORE I USE HRT: PROGESTERONE?

Warnings

Do not use HRT: Progesterone if:

- you are allergic to Progesterone, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine. Some of the symptoms of an allergic reaction may include:
 - shortness of breath;
 - wheezing or difficulty breathing;
 - swelling of the face, lips, tongue or other parts of the body;
 - rash, itching or hives on the skin.
- You are currently taking other forms of Progesterone, including in supplements (e.g. St John's wort) or medicines (e.g.





- anticoagulants) which effect this treatment as it may increase risk of side effects.
- Ask your doctor or pharmacist if you are not sure if you have been taking one of these medicines. Always check the ingredients to make sure you can use this medicine.
- Do not take HRT: Progesterone if the packaging is torn or shows signs of tampering.
- Do not take HRT: Progesterone if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

Check with your doctor if you:

- you are allergic to any other medicines, foods, dyes, or preservatives take any medicines for any other condition
- you have or have had any other health problems or medical conditions, including:
 - Problems with your kidneys, liver or heart
 - A history of hormone-sensitive cancers
 - Are pregnant/breastfeeding

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 <u>6. Are there any side effects?</u>

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

Your doctor will discuss the benefits and risks of using HRT: Progesterone when pregnant or breastfeeding.

3. WHAT IF I AM TAKING OTHER MEDICINES?

Some medicines may interfere with HRT: Progesterone and affect how it works.

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.

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

4. HOW DO I USE HRT: PROGESTERONE?

How much to take / use

- Follow the instructions provided and use HRT: Progesterone until your doctor tells you to stop.
- A variety of factors are taken into consideration when developing a treatment regimen and dosing needs to be titrated to individual requirements.

Oral Capsules:

- Take dose as specified by your doctor.
- Swallow the capsule(s) whole with a full glass of water. Do not chew or crush.

Oral Troches:

- Take dose as specified by your doctor.
- Place the troche in your mouth and allow it to dissolve completely. Do not chew or swallow whole.

Topical Creams:

- Take dose as specified by your doctor.
- Wash your hands before applying.
- Apply a thin layer to the affected area and gently rub it in. Rotate sites to ensure efficacy.
- Avoid contact with eyes, mouth, and broken skin unless specified..

Vaginal Pessary:

Do NOT swallow the capsule. It is for vaginal use ONLY.

 It may be best to use this immediately before bed.





- Wash your hands and vaginal region using mild soap and water
- Lower into a squatting position, or lie on your back and bend your knees with your legs lightly apart
- Using your finger or an applicator, insert the boric acid capsule as far into your vagina as it can comfortably go.
- Wash your hands.

If you forget to use HRT: Progesterone

HRT: Progesterone should be used regularly at the same time each day. If you miss your dose at the usual time, do not take a double dose to make up for the dose you missed.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much HRT: Progesterone

If you think that you have used too much HRT: Progesterone, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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.

If you take too much HRT: Progesterone, you may experience:

- Allergic reactions (rash, itching, swelling, difficulty breathing)
- Headaches, dizziness
- Tenderness especially in breast/chest area
- Blood clots
- Liver issues

5. WHAT SHOULD I KNOW WHILE USING HRT: PROGESTERONE?

Things you should do

Keep all your doctor's appointments so your progress can be checked.

Your doctor may do some tests from time to time to prevent unwanted side effects.

Call your doctor straight away if you:

- are about to be started on any new medicines, remind your doctor or pharmacist that you are taking HRT: Progesterone.
- are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during the surgery.

- If you become pregnant while taking this medicine, tell your doctor immediately.
- If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests. Remind any doctor, dentist or pharmacist you visit that you are using HRT: Progesterone.

Things you should not do

- Do not take HRT: Progesterone to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not take more than the recommended dose.
- Do not stop taking your medicine or change the dosage without checking with your doctor.
- If you stop taking it suddenly, your condition may worsen, or you may have unwanted sideeffects..

Driving or using machines

Be careful before you drive or use any machines or tools until you know how HRT: Progesterone affects you.

This medicine may cause dizziness or a feeling of unsteadiness in some people. If you have any of these





symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your medicine in their container until it is time to use them. If you take the treatment out of their container they may not keep well. Discard unused/left out medication appropriately.
- Keep HRT: Progesterone in a cool, dry place where it stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

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

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a half metres above the ground is a good place to store medicines.

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?

HRT: Progesterone helps most people with MS, but it may have unwanted side effects in some people.

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.

Less serious side effects

Less serious side effects	What to do
Genitourinary issues: Discomfort, cramping Tenderness in chest/breasts Bloating sensation Water retention Irregular menstrual bleeding Allergic Reactions: Rash Itching Non-specific issues: Fatigue or Drowsiness Headache Mood changes Anxiety Irritability	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Systemic issues: Blood clots (VTE, DVT, PE) Stroke Heart disease Liver issues Endometrial cancers Allergic reaction-related: Difficulty breathing (shortness of breath) Swelling of the face, mouth, lips, throat, or tongue Reddening or itching of the skin	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. Serious side effects are
These are very serious side effects. You may need urgent medical attention or hospitalisation.	rare.





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. 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 HRT: Progesterone contains

Active ingredient	Progesterone
(main ingredient)	
Other ingredients	Capsule E4M
(inactive ingredients)	Troche base
	Cream base
Potential	None
allergens	

HRT: Progesterone does not contain lactose, sucrose, gluten, tartrazine, or any other azo dyes.

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

Who distributes HRT: Progesterone

The Compounding Lab

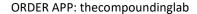
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ORDER ONLINE: www.compoundinglab.com.au



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