

# ORIPRO<sup>®</sup> Progesterone 100mg and 200mg

## 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 ORIPRO<sup>®</sup>?

ORIPRO<sup>®</sup> contains the active ingredient progesterone. ORIPRO<sup>®</sup> is indicated for (1) Assisted reproductive technology (ART) treatment of infertile women with progesterone deficiency, requiring progesterone supplementation or replacement to support embryo implantation and maintain initial pregnancy, (2) Prevention of preterm birth in singleton pregnancies at risk due to; shortened cervix (midtrimester sonographic cervix  $\leq 25\text{mm}$ ) and/or where there is a history of spontaneous preterm birth.

For more information, see Section [1. Why am I using ORIPRO<sup>®</sup>?](#) in the full CMI.

### 2. What should I know before I use ORIPRO<sup>®</sup>?

Do not use if you have ever had an allergic reaction to ORIPRO<sup>®</sup> 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 are breastfeeding.**

For more information, see Section [2. What should I know before I use ORIPRO<sup>®</sup>?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ORIPRO<sup>®</sup> 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 ORIPRO<sup>®</sup>?

Your doctor or pharmacist will tell you how many pessaries you need to use each day. ORIPRO<sup>®</sup> is intended to be inserted into the vagina.

More instructions can be found in Section [4. How do I use ORIPRO<sup>®</sup>?](#) in the full CMI.

### 5. What should I know while using ORIPRO<sup>®</sup>?

|                                    |   |
|------------------------------------|---|
| <b>Things you should do</b>        | <ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using ORIPRO<sup>®</sup>.</li><li>• If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are using ORIPRO<sup>®</sup>.</li></ul>  |
| <b>Things you should not do</b>    | <ul style="list-style-type: none"><li>• Do not give ORIPRO<sup>®</sup> to anyone else, even if they have the same conditions as you.</li><li>• Do not use ORIPRO<sup>®</sup> to treat any other complaints unless your doctor or pharmacist tells you to.</li><li>• Do not stop using ORIPRO<sup>®</sup>, or lower the dosage, without checking with your doctor or pharmacist.</li></ul> |
| <b>Driving or using machines</b>   | <ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how ORIPRO<sup>®</sup> affects you. Some people may feel dizzy or sleepy when using ORIPRO<sup>®</sup>.</li></ul>  |
| <b>Drinking alcohol</b>            | <ul style="list-style-type: none"><li>• If you drink alcohol, dizziness or light-headedness may be worse.</li></ul>   |
| <b>Looking after your medicine</b> | <ul style="list-style-type: none"><li>• Keep your pessaries in their original packaging until it is time to use them. Store below 25°C.</li></ul>   |

For more information, see Section [5. What should I know while using ORIPRO<sup>®</sup>?](#) in the full CMI.

### 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, typically they are minor and temporary. However, some side effects may need medical attention. Most common side effects include local irritation or itching, weight gain, abdominal cramping, bloating, swelling of face, ankles and feet, headache, dizziness, and drowsiness, unusual tiredness, or weakness, abnormal breakthrough uterine and/or vaginal bleeding or, spotting, or changes in cervical secretions, loss of menstruation, dry mouth, loss of appetite, and unusual thirst (diabetes, hyperglycaemia). Serious side effects include migraine, loss of or change of speech, coordination or vision, pain or numbness in chest, arm or leg; unexplained shortness of breath, any symptoms of blood clots (thrombosis) and jaundice.

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.

# ORIPRO<sup>®</sup>

Active ingredient(s): Progesterone 100mg, and 200mg

## Consumer Medicine Information (CMI)

This leaflet provides important information about using ORIPRO<sup>®</sup>. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about ORIPRO<sup>®</sup>.**

Where to find information in this leaflet:

- [1. Why am I using ORIPRO<sup>®</sup>?](#)
- [2. What should I know before I use ORIPRO<sup>®</sup>?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ORIPRO<sup>®</sup>?](#)
- [5. What should I know while using ORIPRO<sup>®</sup>?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using ORIPRO<sup>®</sup>?

**ORIPRO<sup>®</sup> contains the active ingredient progesterone.**

Progesterone is a female hormone. ORIPRO<sup>®</sup> is specially made to insert in your vagina.

ORIPRO<sup>®</sup> can be given to women undergoing fertility treatment. Progesterone is a hormone essential for maintaining pregnancy. If you are having fertility treatment and your doctor has determined your body does not produce enough progesterone they may prescribe ORIPRO<sup>®</sup>.

The progesterone will help prepare your uterus to receive and maintain a fertilised egg. Once pregnancy occurs, ORIPRO<sup>®</sup> may be used until production of progesterone by the placenta is adequate.

Your doctor may prescribe ORIPRO<sup>®</sup> 100mg or 200mg from the second trimester of your pregnancy, to prevent you going into labour too early. ORIPRO<sup>®</sup> will not be prescribed to prevent early labour if you are expecting more than one baby.

ORIPRO<sup>®</sup> is not addictive.

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

ORIPRO<sup>®</sup> is not recommended in children, as the safety and effectiveness of progesterone in this age group has not been established.

## 2. What should I know before I use ORIPRO<sup>®</sup>?

### Warnings

**Do not use ORIPRO<sup>®</sup> if:**

- you are allergic to progesterone, or any of the ingredients listed at the end of this leaflet.

- Symptoms of an allergic reaction to progesterone may include:
  - shortness of breath, wheezing or difficulty breathing
  - swelling of the face, lips, tongue or other parts of the body
  - skin rash, itching or hives.
- you have or have had any of the following medical conditions:
  - undiagnosed vaginal bleeding
  - undiagnosed urinary tract bleeding
  - active blood clotting (thrombophlebitis or thrombo-embolic disorder), such as, inflammation of a vein, deep vein blood clotting (thrombosis), or a blood clot that travelled to the lungs (pulmonary embolism)
  - a history of hormone associated thrombophlebitis or thrombo-embolic disorder
  - liver dysfunction or disease
  - malignancy or tumours, known or suspected of breast or genital organs
  - pregnancy (when normal progesterone levels are present)
  - missed abortion.
- Always check the ingredients to make sure you can use this medicine.

### Before you start to use ORIPRO<sup>®</sup>:

Before starting or recommencing progesterone therapy, a physical examination should have been performed, including special attention to the breasts, abdomen and pelvic organs and a Cervical Screening Test.

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- Conditions that might be made worse by a build-up of fluid (fluid retention), for example: asthma, seizure disorders (epilepsy), migraine, or cardiac or renal dysfunction.
- History of mental depression; stop use if serious depression recurs during therapy.
- Diabetes as high doses of progesterone therapy can lower glucose tolerance in some patients.
- History of liver disease or dysfunction as progesterone is metabolised in the liver.
- Disturbed cholesterol or lipid metabolism (hyperlipidemia) as progesterone may increase Low Density Lipoproteins (LDL) and lower High Density Lipoproteins (HDL) levels and worsen problems in controlling hyperlipidemia.

- Active inflammation of a vein usually with a clot (thrombophlebitis) or clotting (thrombo-embolic) disorders or a history of hormone associated thrombophlebitis or thrombo-embolic disorders.

Tell your doctor if you have any risk factors for preterm labour such as:

- pre-existing or gestational diabetes
- pre-existing conditions such as hepatitis C, human papilloma virus and hyperthyroidism
- have a history of gynaecological conditions
- vaginal infections and/or bleeding from the vagina
- smoke
- drink alcohol
- overweight or obese
- exposure to certain environmental pollutants.

Safety and efficacy of ORIPRO® in women with these risk factors have not been established.

If you have not told your doctor or pharmacist about any of the above, tell them before you start using ORIPRO®.

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

**Do not use ORIPRO® if you are pregnant and have normal progesterone levels unless your doctor tells you to:**

Progesterone is not recommended for use in normal pregnancy where normal progesterone levels exist.

Where progesterone levels are insufficient or low and you and your doctor have discussed the risks and benefits involved, as in assisted reproductive procedures, ORIPRO® is used to support embryo implantation, and to instigate and maintain initial pregnancy. No adverse effects have been reported when used in this manner.

Your doctor or pharmacist will discuss the possible risks and benefits of using ORIPRO® during pregnancy.

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

ORIPRO® is not recommended while you are breast-feeding. If there is a need to consider ORIPRO® while you are breast-feeding, your doctor or pharmacist will discuss with you the benefits and risks of using them. Progesterone passes into the breast milk in variable amounts and may affect the quantity of breast milk. The effect of the progesterone on the breastfeeding infant is not known.

**Do not give or use ORIPRO® to a child of any age.**

The safety and effectiveness of progesterone use in children has not been established.

If you are not sure whether you should start using ORIPRO®, talk to your doctor or pharmacist.

## 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.

**Some medicines may interfere with ORIPRO® and affect how it works.**

These include:

- Carbamazepine, Phenobarbital, and Phenytoin (medicines for epilepsy)
- Rifabutin, Rifampicin and
- Aminoglutethimide

These medicines may be affected by ORIPRO® or may affect how well they work. You may need different amounts of your medicine, or you may need to use different medicines. Your doctor or pharmacist will advise you.

Use of other vaginal products should be avoided during use of ORIPRO®.

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

## 4. How do I use ORIPRO®?

**How much to use:**

**Your doctor or pharmacist will tell you how many pessaries you need to use each day.**

**ORIPRO® is intended to be inserted into the vagina**

1. Wash your hands thoroughly with soap and water.
2. Feel the pessary while it is still in the wrapper. If it feels soft, keep it in the wrapper and chill it in the fridge for a few minutes. Do not remove the wrapper while you are chilling it.
3. Put on a disposable glove, if desired. These are available from pharmacies.
4. Remove wrapper from one pessary.
5. If you are particularly dry and insertion feels uncomfortable you may need to moisten the pessary by dipping it briefly in cool water, before insertion. Either using a squatting position or lying on your back or side, insert the pessary deep into the vagina.
6. Depending on dosage, the best time for a pessary to be inserted may be before retiring at night. But if more than one dose is necessary, a second dose could be inserted in the morning.
10. Throw away any used materials and wash your hands thoroughly.

**If you are not sure how to use a pessary, ask your doctor or pharmacist.**

## When to use ORIPRO®

When undergoing fertility treatment: Use ORIPRO® at the same time each day as directed by your doctor.

For the prevention of preterm labour: Use ORIPRO® pessaries each night before bed.

## How long to use ORIPRO®:

Do not stop using ORIPRO® unless your doctor or pharmacist tells you to.

## If you forget to use ORIPRO®

If it is almost time for your next dose, (within 4 hours), skip the dose you missed and use your next dose when you are meant to, as usual.

Otherwise, use it as soon as you remember, and then go back to using your medicine as you would normally.

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

This may increase the chance of you getting unwanted side effects.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

## If you use too much ORIPRO®

If you think that you have used too much ORIPRO®, 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.

Symptoms of an overdose with ORIPRO® include the side effects listed below in the 'Side Effects' section, but are usually of a more severe nature.

### What to do if someone has swallowed some pessaries accidentally.

If someone has swallowed some pessaries, there is no need for great concern. However, you should consult your doctor. Symptoms that may arise are euphoria, nausea, vomiting or dysmenorrhoea may develop. No specific antidote is known. Symptomatic and supportive treatment can be given if necessary.

## 5. What should I know while using ORIPRO®?

### Things you should do

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

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

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are using ORIPRO®.

### Things you should not do

**Do not give ORIPRO® to anyone else, even if they have the same conditions as you.**

Do not use ORIPRO® to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop using ORIPRO®, or lower the dosage, without checking with your doctor or pharmacist.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how ORIPRO® affects you.**

ORIPRO® may cause dizziness or drowsiness in some people. Make sure you know how you react to ORIPRO® before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

If you drink alcohol, dizziness or light-headedness may be worse.

### Looking after your medicine

Keep your pessaries in their original packaging until it is time to use them.

If you take pessaries out of the packaging they will not keep well.

Keep your pessaries in a cool dry place away from moisture, heat or sunlight where the temperature stays below 25°C 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.

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

Do not use ORIPRO® if the packaging is damaged or shows signs of tampering or the product does not look quite right.

**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 ORIPRO® after the expiry date.

## 6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using ORIPRO®.

ORIPRO® helps most women with progesterone insufficiency, but it may have unwanted side effects in a few women. 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. Do not be alarmed by this list. You may not experience any of them.

### Less serious side effects

| Less serious side effects   | What to do  |
|---|---|
| <p><b>Skin related:</b></p> <ul style="list-style-type: none"> <li>Local irritation or itching may occur in sensitive persons, at the site of insertion when treatment is started.</li> <li>Loss or gain of body facial or scalp hair or brown spots on exposed skin (melasma).</li> <li>Acne</li> </ul> <p><b>Metabolism and nutrition related:</b></p> <ul style="list-style-type: none"> <li>Weight gain.</li> </ul> <p><b>Reproductive system related:</b></p> <ul style="list-style-type: none"> <li>Breast pain or tenderness, hot flushes.</li> </ul> <p><b>Gastrointestinal system related:</b></p> <ul style="list-style-type: none"> <li>Abdominal cramping, bloating</li> </ul> <p><b>Lymphatic system related:</b></p> <ul style="list-style-type: none"> <li>Swelling of face, ankles and feet (oedema)</li> </ul> <p><b>Nervous system related:</b></p> <ul style="list-style-type: none"> <li>Mild mood changes, nervousness, changes in libido, and insomnia</li> </ul> <p><b>Endocrine system related:</b></p> <ul style="list-style-type: none"> <li>nausea and vomiting, unusual tiredness, or weakness.</li> </ul> <p><b>Cardiac system related:</b></p> <ul style="list-style-type: none"> <li>Increased blood pressure in susceptible individuals.</li> </ul> | <p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> |

### Serious side effects

| Serious side effects  | What to do   |
|---|--|
| <p><b>Reproductive system related:</b></p> <ul style="list-style-type: none"> <li>Abnormal breakthrough uterine and/or vaginal bleeding or, spotting, or changes in cervical secretions.</li> </ul> | <p><b>Tell your doctor as soon as possible if you notice any of the following.</b></p> |

|   |  |
|---|--|
| <ul style="list-style-type: none"> <li>Loss of menstruation (amenorrhoea).</li> </ul> <p><b>Metabolism and nutrition related:</b></p> <ul style="list-style-type: none"> <li>Dry mouth, loss of appetite, and unusual thirst (diabetes, hyperglycaemia).</li> </ul> <p><b>Urinary system related</b></p> <ul style="list-style-type: none"> <li>Frequent urination</li> </ul> <p><b>Nervous system related:</b></p> <ul style="list-style-type: none"> <li>Headache, dizziness, and drowsiness.</li> </ul> <p><b>Psychiatric related:</b></p> <ul style="list-style-type: none"> <li>Mental depression.</li> </ul> <p><b>Skin related:</b></p> <ul style="list-style-type: none"> <li>Skin rash, itchiness (pruritus).</li> </ul> |  |
| <p><b>Various:</b></p> <ul style="list-style-type: none"> <li>Loss of or change of speech, coordination or vision, pain or numbness in chest, arm or leg; unexplained shortness of breath, any symptoms of blood clots (thrombosis)</li> </ul> <p><b>Hepatobiliary system related:</b></p> <ul style="list-style-type: none"> <li>Yellowing of skin or eyes (jaundice).</li> </ul> <p><b>Nervous system related:</b></p> <ul style="list-style-type: none"> <li>Migraine</li> </ul>   | <p><b>If any of the following happen, stop using ORIPRO®, and tell your doctor immediately or go to the Emergency Department at your nearest hospital.</b></p> |

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](http://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 ORIPRO® contains

|   |              |
|---|--------------|
| <b>Active ingredient (main ingredient)</b>      | Progesterone |
| <b>Other ingredients (inactive ingredients)</b> | Hard fat     |

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

### **What ORIPRO® looks like**

Opaque, bullet-shaped waxy, solid masses, containing 100mg or 200mg progesterone supplied either as blisters in a unit carton or individual pessaries in a glass jar.

\* Not all pack sizes are marketed.

Pack size: 5, 15 or 30

ORIPRO® progesterone 100mg pessary strip pack  
(Aust R 165111)

ORIPRO® progesterone 200mg pessary strip pack  
(Aust R 165112)

ORIPRO® progesterone 100mg pessary jar (Aust R 21190)

ORIPRO® progesterone 200mg pessary jar (Aust R 21195)

### **Who distributes ORIPRO®**

Orion Laboratories Pty Ltd T/A Evaris Pharma  
25-29 Delawney Street,  
Balcatta, WA 6021

This leaflet was prepared in November 2025.