

Consumer Medicine Information**What is in this leaflet**

This leaflet answers some common questions about Oriprio.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you taking Oriprio against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Oriprio is used for

Oriprio is specially made to insert in your vagina. They contain a female hormone called progesterone.

Oriprio 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 Oriprio.

The progesterone will help prepare your uterus to receive and maintain a fertilized egg. Once pregnancy occurs, Oriprio may be used until production of progesterone by the placenta is adequate.

Your doctor may prescribe Oriprio 200 mg from the second trimester of your pregnancy, to prevent you going into labour too early. Oriprio will not be prescribed to prevent early labour if you are expecting more than one baby.

Oriprio is not addictive.

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

Oriprio is not recommended in children, as the safety and effectiveness of progesterone in this age group has not been established.

Before you use Oriprio**When you must not use Oriprio:**

Do not use Oriprio if you have an allergy 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

Do not use Oriprio if 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

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

Progesterone is not recommended for use in normal pregnancy unless your doctor prescribes it from your second trimester to prevent preterm labour.

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

Do not use Oriprio if you are breast-feeding or plan to breast-feed:

Progesterone passes into the breast milk in variable amounts and may affect the quantity of breast milk. The effect of the progesterone on the breast feeding infant is not known.

Do not give or use Oriprio to a child of any age.

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

Do not use Oriprio after the expiry date printed on the pack.

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

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to use Oriprio:

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 Papanicolaou (Pap) smear.

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 buildup 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 labor 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 Oriprio in women with these risk factors have not been established.

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant:

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

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed.

Oriprio is not recommended while you are breast-feeding. If there is a need to consider Oriprio 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 breast feeding infant is not known.

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

Taking other medicine:

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

Some medicines and progesterone may interfere with each other. These include:

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

These medicines may be affected by Oriprio 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 Oriprio.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while using Oriprio.

How to use Oriprio

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

Oriprio is intended to be inserted into the vagina.

Follow these steps to use a pessary:

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.
7. 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 Oriprio:

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

For the prevention of preterm labour: Use Oriprio 200 mg pessaries each night before bed.

How long to use Oriprio:

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

If you forget to use Oriprio:

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 many pessaries (overdose):

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too many pessaries.

Symptoms of an overdose with Oriprio 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, or nausea, vomiting or dysmenorrhoea may develop. No specific antidote is known. Symptomatic and supportive treatment can be given if necessary.

While you are using Oriprio

Things you must do:

Tell any other doctors, dentists, and pharmacists who are treating you that you are using Oriprio.

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

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

If you become pregnant while using Oriprio, tell your doctor or pharmacist.

Things you must not do:

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

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

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

Things to be careful of:

Be careful driving or operating machinery until you know how Oriprio affects you.

Oriprio may cause dizziness or drowsiness in some people. Make sure you know how you react to Oriprio 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. If you drink alcohol, dizziness or light-headedness may be worse.

Side effects

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

Oriprio helps most women with progesterone insufficiency, but it may have unwanted side effects in a few women. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Following is a list of possible side effects. Do not be alarmed by this list.

You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Local irritation or itching may occur in sensitive persons, at the site of insertion when treatment is started.
- Abdominal cramping, bloating, swelling face, ankles and feet (oedema).
- Unusual tiredness, or weakness or weight gain.
- Nausea and vomiting.

- Acne, breast pain or tenderness, hot flushes.
- Mild mood changes, nervousness, changes in libido, and insomnia.
- Increased blood pressure in susceptible individuals.
- Loss or gain of body facial or scalp hair or brown spots on exposed skin (melasma).

These are the more common side effects of Oriprio. (Mostly these are mild and short lived).

Tell your doctor as soon as possible if you notice any of the following:

- Abnormal breakthrough uterine and/or vaginal bleeding or, spotting, or changes in cervical secretions.
- Headache, dizziness, and drowsiness.
- Loss of menstruation (amenorrhoea).
- Dry mouth, frequent urination, loss of appetite, and unusual thirst (diabetes, hyperglycaemia).
- Mental depression.
- Skin rash, itchiness (pruritus).

These may be serious side effects. You may need medical attention. (Serious side effects are rare).

If any of the following happen, stop using Oriprio, and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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).
- Yellowing of skin or eyes (jaundice).

These are very serious side effects. You may need urgent medical attention or hospitalisation. (These side effects are very rare).

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After using Oriprio

Storage

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 where the temperature stays below 25°C.

Do not store Oriprio or any other medicine in the bathroom or near a sink.

Do not leave Oriprio on a window sill or in the car on hot days.

Heat and dampness can destroy some medicines.

Keep Oriprio where children cannot reach them.

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

Disposal

If your doctor or pharmacist tells you to stop using Oriprio or they have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product Description

What it 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 marketed).

Pack size: 5 (strip pack only - samples) 15 or 30.

Ingredients

Active ingredient:

- 100mg or 200mg of progesterone.

Other ingredients:

- hard fat.

Manufacturer/Distributor

Orion Laboratories Pty Ltd T/A Perrigo
Australia
25-29 Delawney Street
Balcatta WA 6021

ARTG Numbers:

AUST R 21190, AUST R 21195, AUST R 165111 and AUST R 165112.

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