

# ENDOMETRIN® Pessaries

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## 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.

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### 1. Why am I using ENDOMETRIN?

ENDOMETRIN contains the active ingredient progesterone, a naturally occurring sex hormone. It is given to women who need extra progesterone while undergoing fertility treatment in an Assisted Reproductive Technology (ART) programme (e.g. In Vitro Fertilisation (IVF)).

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

### 2. What should I know before I use ENDOMETRIN?

Do not use ENDOMETRIN if you have ever had an allergic reaction to any medicine containing progesterone or any of the ingredients listed at the end of the CMI, see Section [7. Product details.](#)

**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 ENDOMETRIN?](#) in the full CMI.

### **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 ENDOMETRIN and affect how it works. For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I use ENDOMETRIN?**

The usual dosage is one 100 mg pessary (vaginal tablet) placed directly into the vagina two or three times daily, depending on your needs, following egg retrieval. Your doctor or pharmacist will tell you when to start using ENDOMETRIN and how many tablets you need to use each day.

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

## 5. What should I know while using ENDOMETRIN?

<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 ENDOMETRIN.</li><li>• Tell your doctor immediately if you experience pain in your calves or chest, sudden shortness of breath, coughing blood, severe headache or vomiting, faintness or changes in vision or speech, weakness or numbness of an arm or leg and worsening depression while using ENDOMETRIN.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly or lower the dosage, without checking with your doctor.</li><li>• Do not give your medicine to anyone else, even if they have</li></ul>

	the same condition as you.
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• ENDOMETRIN may cause dizziness in some people.</li> <li>• Be careful before you drive or use any machines or tools until you know how ENDOMETRIN affects you.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Store it in a cool dry place, where the temperature stays below 25°C, away from moisture, heat or sunlight. Keep this medicine in its original packaging until it is time to use them.</li> </ul>

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

## 6. Are there any side effects?

All medicines can have side effects. Most of them are minor and temporary but some may need medical attention.

**Tell your doctor if you experience any side effects, including rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing. These are very serious side effects. You may need urgent medical attention.**

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.

# ENDOMETRIN® Pessaries

Active ingredient: Progesterone

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using ENDOMETRIN. **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 ENDOMETRIN.**

**Where to find information in this leaflet:**

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

## 1. Why am I using ENDOMETRIN?

ENDOMETRIN contains the active ingredient, progesterone, a naturally occurring sex hormone. It is given to women who need extra progesterone while undergoing treatment in an Assisted Reproductive Technology (ART) programme (e.g. IVF).

Progesterone acts on the lining of the uterus (womb) and it helps you to become pregnant and maintain pregnancy when you are treated for infertility.

ENDOMETRIN is available as a pessary (vaginal tablet).

**Ask your doctor if you have any questions about why ENDOMETRIN has been prescribed for you.**

Your doctor may have prescribed ENDOMETRIN for another reason.

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

## **2. What should I know before I use ENDOMETRIN?**

### **Warnings**

#### **Do not use ENDOMETRIN if:**

- you are allergic to progesterone, or any of the ingredients listed at the end of this leaflet. Your doctor should make you aware of the signs and symptoms that may indicate an allergic reaction when using ENDOMETRIN.

- you have or have had any of the following conditions:
  - unusual vaginal bleeding that has not been evaluated by your doctor
  - miscarriage, missed abortion or ectopic pregnancy (pregnancy outside of the womb)
  - severe liver problems
  - known or suspected cancer of the breast or genital tract
  - blood clots in the legs, lungs, eyes or elsewhere in the body
  - porphyria disorder (a blood disease).
- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering.

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

### **Check with your doctor if you:**

- have any other medical conditions
- take any medicines for any other condition
- are not sure whether you should use this medicine.

### **Other medical conditions you need to tell your doctor about include:**

- • epilepsy
- • migraine
- • asthma
- • heart, liver or kidney disease



- • diabetes
- • history of depression.

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**

During fertility treatment ENDOMETRIN should only be used during the first three months of pregnancy, unless your doctor has recommended otherwise.

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

The exposure to external progesterone during pregnancy has not been fully established.

**Do not use ENDOMETRIN if you are breast-feeding.**

### **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 ENDOMETRIN and affect how it works.

**Medicines that may increase the effect of ENDOMETRIN include:**

- ketoconazole (medicine for fungal infection), antifungal medicine

**Medicines that may reduce the effect of ENDOMETRIN include:**

- rifampicin (antibacterial medicine for tuberculosis, leprosy and some bacterial infections)
- carbamazepine (medicine for epilepsy)
- • St John's Wort (Hypericum perforatum - a herbal product ingredient)

**ENDOMETRIN should not be used at the same time as other vaginal preparations (such as antifungal products).**

Your doctor or pharmacist has more information on medicines to be careful with or avoid while are you using this medicine.

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

## **4. How do I use ENDOMETRIN?**

### **How much to use**

**Your doctor or pharmacist will tell you when to start and how many tablets you need to use each day.**

- The usual dosage is one 100 mg tablet placed directly into the vagina two or three times daily, depending on your needs, following egg retrieval. Your doctor will advise you of the appropriate dose for you.
- Follow the instructions provided and use ENDOMETRIN until your doctor tells you to stop.

## **When to use ENDOMETRIN**

- ENDOMETRIN should be used following egg retrieval
- The use of ENDOMETRIN may be continued for up to 10 weeks total duration if pregnancy is confirmed (or 12 weeks of gestation).

## **How to use ENDOMETRIN**

**ENDOMETRIN vaginal tablets are intended to be placed directly into the vagina.**

An applicator is provided in the pack to help administer the tablets.

Follow the directions on how to administer the tablet below:

- wash your hands thoroughly with soap and water
- unwrap the applicator and remove one vaginal tablet from the blister pack
- put one tablet in the space provided at the end of the applicator. The tablet should fit securely and not fall out
- the applicator with the tablet may be inserted into the vagina while you are standing, sitting, or when lying on

your back with your knees bent. Gently insert the thin end of the applicator well into the vagina

- push the plunger to release the tablet
- remove the applicator and rinse it thoroughly in warm running water, wipe dry with a soft tissue and keep the applicator for subsequent use.

The directions on how to administer the tablet are also provided with each pack of ENDOMETRIN.

**If you do not understand the instructions, ask your doctor or pharmacist for help.**

## **If you forget to use ENDOMETRIN**

ENDOMETRIN should be used regularly at the same time each day.

If you miss your dose at the usual time:

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

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

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

## **If you stop using ENDOMETRIN**

Please consult your doctor or pharmacist for advice if you intend to stop or have stopped using ENDOMETRIN.

If you stop using ENDOMETRIN suddenly, you may experience increased anxiety, moodiness and increased sensitivity to seizures.

## **If you use too much ENDOMETRIN**

If you think that you have used too much ENDOMETRIN, 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.**

## **5. What should I know while using ENDOMETRIN?**

### **Things you should do**

#### **Call your doctor straight away if you experience:**

- pains in your calves or chest, a sudden shortness of breath or coughing blood indicating possible clots in the legs, heart or lungs
- severe headache or vomiting, dizziness, faintness or changes in vision or speech, weakness or numbness of an arm or leg indicating possible clots in the brain or eye
- worsening symptoms of depression.

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

### **Things you should not do**

- Do not stop using this medicine suddenly or lower the dosage, without checking with your doctor or pharmacist.
- Do not give ENDOMETRIN to anyone else, even if they have the same condition as you.
- Do not use ENDOMETRIN to treat any other complaints unless your doctor has told you to.

## **Driving or using machines**

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

ENDOMETRIN may cause dizziness or drowsiness in some people.

Make sure you know how you react to ENDOMETRIN 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.

## **Looking after your medicine**

**Keep this medicine in its original packaging until it is time to use it.**

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

Store it in a cool dry place where the temperature stays below 25°C 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.**

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

## When to discard your medicine

### 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 located on the carton. The expiry date refers to the last day of that month.

## 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><b>Common side effects (affect more than 1 in 100 users):</b></p> <ul style="list-style-type: none"><li>• Headache</li><li>• Abdominal distension (bloating or swelling in the abdomen)</li></ul>	<p><b>These side effects are not usually serious but can become serious.</b></p>



<b>Side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• Abdominal pain</li> <li>• Nausea</li> <li>• Vulvovaginal disorders (such as discomfort, burning sensation, discharge, dryness and bleeding)</li> <li>• Uterine cramping</li> </ul> <p><b>Uncommon side effects (affect less than 1 in 100 users):</b></p> <ul style="list-style-type: none"> <li>• Dizziness</li> <li>• Insomnia (difficulty sleeping)</li> <li>• Diarrhoea</li> <li>• Constipation</li> <li>• Urticaria (allergic rash)</li> <li>• Rash</li> <li>• Fungal infections in the vagina (e.g. vaginal thrush)</li> <li>• Breast disorders (e.g. breast pain, breast swelling and breast tenderness)</li> <li>• Itching in the genital area</li> </ul>	<p><b>Speak to your doctor if you have any of these side effects and they worry you.</b></p>

<b>Side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• Swelling of the limbs (due to fluid build-up)</li> </ul> <p><b>Unknown frequency:</b></p> <ul style="list-style-type: none"> <li>• Fatigue (tiredness)</li> <li>• Vomiting</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Allergic reactions (unknown frequency):</b></p> <ul style="list-style-type: none"> <li>• Rash, itching or hives on the skin</li> <li>• Swelling of the face, lips, tongue or other parts of the body</li> <li>• Shortness of breath, wheezing or difficulty breathing</li> </ul>	<p><b>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.</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 ENDOMETRIN contains

<b>Active ingredient (main ingredient)</b>	100 milligrams of progesterone (micronised)
<b>Other ingredients (inactive ingredients)</b>	Colloidal anhydrous silica, lactose monohydrate, pregelatinised maize starch, povidone, adipic acid, sodium bicarbonate, sodium lauryl sulfate, magnesium stearate

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

## **What ENDOMETRIN looks like**

This medicine is a vaginal tablet.

ENDOMETRIN is a white to off-white, convex and oblong tablets with the inscriptions "FPI" on one side and "100" on the other side.

It is supplied in blister strips packaged in an outer carton. Each carton contains 21 tablets and one vaginal applicator.

(AUST R 189948).

## **Who distributes ENDOMETRIN**

ENDOMETRIN is distributed in Australia by:

Ferring Pharmaceuticals Pty Ltd

Suite 2, Level 1, Building 1,

20 Bridge Street, Pymble NSW 2073

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