

# UTROGESTAN 200, 300 and 400<sup>®</sup>

## 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 UTROGESTAN ?

UTROGESTAN contains the active ingredient progesterone. UTROGESTAN is used for women who need extra progesterone while undergoing fertility treatment (e.g. ART); for the treatment of unexplained threatened miscarriage; for the prevention of preterm birth in women with a short cervix and or history of spontaneous preterm birth.

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

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

Do not use if you have ever had an allergic reaction to UTROGESTAN or any of the ingredients listed at the end of the CMI. Do not use if you are breast-feeding.

**Talk to your doctor if you have any other medical conditions or are taking any other medicines.**

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

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

Some medicines may interfere with UTROGESTAN 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 UTROGESTAN?

- UTROGESTAN should be used as instructed by your doctor at the recommended dose and timeframes for each use. UTROGESTAN is intended to be inserted into the vagina.

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

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

<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 UTROGESTAN.</li><li>• Follow all direction given to you by your doctor carefully.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not use if you have unusual vaginal bleeding that has not been evaluated by your doctor,</li><li>• Do not use if you have known missed abortions or ectopic pregnancy</li><li>• Do not use if you have or are suspected of having cancer of the breast or genital tract</li><li>• Do not use if you have a blood clot or bleeding on the brain.</li><li>• Do not use if your liver is not working well.</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 UTROGESTAN affects you. Some people may experience drowsiness or dizziness.</li><li>• Make sure you know how you react to UTROGESTAN 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.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Alcohol may increase the effect of UTROGESTAN</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store below 30°C.</li></ul>

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

### 6. Are there any side effects?

**Call your doctor straight away if you** experience swelling of the face, lips, mouth or throat which may cause difficulty swallowing or breathing or hives. Tell your doctor if you notice any of the following and they worry you: burning, local itching, and vaginal disorders. Systemic side effects of tiredness and dizziness observed with the oral form have not been reported at the recommended dosages for vaginal use.

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.

# UTROGESTAN 200, 300 and 400®

Active ingredient(s): Progesterone (micronised)

## Consumer Medicine Information (CMI)

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

### Where to find information in this leaflet:

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

## 1. Why am I using UTROGESTAN?

**UTROGESTAN** contains the active ingredient micronised progesterone. UTROGESTAN is provided as a soft capsule to be inserted deep into the vagina and contains the natural female hormone progesterone. Progesterone is a hormone essential for maintaining pregnancy.

### UTROGESTAN is used for:

- Women who need extra progesterone while undergoing fertility treatment (e.g. ART)  
If you are having fertility treatment and your doctor has determined your body does not produce enough progesterone your doctor may prescribed UTROGESTAN.  
The progesterone will help prepare your uterus (womb) to receive and maintain a fertilised egg.  
Once pregnancy occurs UTROGESTAN may be used until production of progesterone by the placenta is adequate.
- Prevention of preterm birth in women with singleton pregnancy who have a short cervix (midtrimester sonographic cervix  $\leq$  25 mm) and/or a history of spontaneous preterm birth.  
There is limited evidence supporting the use of progesterone with twin/multiple pregnancies.  
There is insufficient evidence to recommend the use of progesterone in women with preterm labour or 'other' risk factors for preterm birth.
- Reducing the risk of miscarriage in women with bleeding in the current pregnancy and a history of three or more previous miscarriages.  
The benefit of this medicine was shown to be limited to women who have had three or more previous miscarriages. However, your doctor may consider it

appropriate to use in women with less than three miscarriages, who have a reduced chance of future pregnancy.

Other known causes of potential miscarriage should be ruled out before starting treatment.

Your doctor may have prescribed UTROGESTAN for another purpose. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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

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

### Do not use UTROGESTAN if:

- you are allergic to progesterone, or any of the ingredients listed at the end of this leaflet.
- you have or have had any of the following conditions:
  - Unusual vaginal bleeding that has not been evaluated by your doctors;
  - Known missed abortions or ectopic pregnancy;
  - Severe liver problems;
  - Known or suspected cancer of the breast or genital tract;
  - Blood clots (thrombophlebitis or thromboembolic disorder), such as inflammation of a vein, deep vein blood clotting (thrombosis) or a blood clot that travelled to the lungs (pulmonary embolism);
  - Bleeding on the brain;
  - Porphyria disorder (a blood disease).

### Warnings

#### Check with your doctor if you:

- have or have had any medical conditions, especially the following:
  - Epilepsy
  - Migraine
  - High blood pressure
  - Asthma
  - Heart, liver or kidney diseases
  - Diabetes
  - History of depression
- Tell your doctor or pharmacist if you have allergies to:
  - Any other medicines
  - Lecithin (UTROGESTAN contains soya lecithin which may cause hypersensitivity reactions)
  - Sulfur dioxide (UTROGESTAN may contain traces of sulfur dioxide <50 ppm)
  - Any other substances, such as foods, preservatives or dyes

**If you have not told your doctor or pharmacist about any of the above, tell them before you use UTROGESTAN.**

- If you think you have miscarried, you should speak to your doctor as you will need to stop using UTROGESTAN.

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?](#)

UTROGESTAN is not suitable for use as a contraceptive.

### **Pregnancy and breastfeeding**

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

For treatment to reduce the risk of miscarriage in women with bleeding in the current pregnancy UTROGESTAN should be initiated at the first sign of vaginal bleeding during the first trimester and should continue at least until the 16<sup>th</sup> week of pregnancy.

For the prevention of preterm birth UTROGESTAN may be prescribed by your Doctor during the second trimester (16 – 24 weeks gestation) and should be continued to the end of the 36<sup>th</sup> week of your pregnancy or until delivery.

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

### **Children and adolescents**

Do not give UTROGESTAN to a child of any age. UTROGESTAN has not been evaluated in adolescents with childbearing potential.

## **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 UTROGESTAN and affect how it works or how these medicines work. These include:**

- Carbamazepine, Phenobarbital and Phenytoin (medicines for epilepsy)
- Rifampicin
- Phenylbutazone
- Spironolactone
- Griseofulvin
- Some antibiotics including Ampicillins and Tetracyclines
- Bromocriptine
- Cyclosporin
- Ketoconazole

These medicines may be affected by UTROGESTAN 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.

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

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

### **How much to use**

**Your doctor will tell you how many capsules you need to use each day.**

- For supplementation during Assisted Reproductive Technology, the recommended dosage is 600 mg/day, in two or three divided doses from the day of embryo transfer until at least the 7<sup>th</sup> week of pregnancy and not later than the 12<sup>th</sup> week of pregnancy.
- For treatment to reduce the risk of miscarriage in women with bleeding in the current pregnancy, the usual dose is 400 mg twice daily from the first sign of vaginal bleeding until at least the 16<sup>th</sup> week of pregnancy.
- For the prevention of preterm birth the usual dose is 200 mg/day recommended at bedtime, during the second trimester (16-24 weeks gestation) and should be continued until the end of the 36<sup>th</sup> week of your pregnancy or until delivery.

### **When to take / use UTROGESTAN**

- UTROGESTAN is intended to be inserted into the vagina.
- Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.
- Do not stop using UTROGESTAN or lower the dosage without checking with your doctor.
- UTROGESTAN should not be used at the same time as other vaginal preparations.

### **If you forget to use UTROGESTAN**

UTROGESTAN should be used as instructed by your doctor for the recommended timeframes for each use.

If you miss a dose, use it as soon as you remember, and then go back to using your medicine as you would normally.

**If it is almost time for your next dose, skip the dose you missed and go back to using your medicine when you are meant to.**

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

### **If you use too much UTROGESTAN**

If you think that you or anyone else may have used too much UTROGESTAN, 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 UTROGESTAN include feeling dizzy or feeling tired.

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

UTROGESTAN contains soya lecithin. If you are allergic to soya do not use UTROGESTAN.

### Things you should do

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

- Experience swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- Hives

You may have had a very serious reaction to UTROGESTAN and may need urgent medical attention or hospitalization.

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

### Things you should not do

- Do not stop using this medicine or lower the dosage without checking with your doctor or pharmacist.
- UTROGESTAN should not be used at the same time as other vaginal preparations.

### Driving or using machines

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

UTROGESTAN may cause drowsiness or dizziness in some people. Make sure you know how you react to UTROGESTAN 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.**

Alcohol may increase the effect of UTROGESTAN.

### Looking after your medicine

Store below 30°C.

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.

### Less serious side effects

Less serious side effects	What to do
<b>Side effects such as:</b> <ul style="list-style-type: none"> <li>• Burning</li> <li>• Local itching</li> <li>• Vaginal disorders</li> </ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<b>Side effects such as:</b> <ul style="list-style-type: none"> <li>• Swelling of the face, lips, mouth or throat which may cause difficulty swallowing or breathing.</li> <li>• Hives</li> </ul>	<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>

Systemic side effects of tiredness and dizziness observed with the oral form have not been reported at the recommended dosages for vaginal use.

**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.  
This medicine is not addictive.

### What UTROGESTAN contains

<b>Active ingredient (main ingredient)</b>	<b>Progesterone 200 mg, 300 mg or 400 mg</b>
<b>Other ingredients (inactive ingredients)</b>	Sunflower oil Lecithin Gelatin Glycerol Titanium dioxide Purified water
<b>Potential allergens</b>	Lecithin (from soya) Traces of Sulfur dioxide (from gelatin <50ppm)

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

### What UTROGESTAN looks like

UTROGESTAN 200 is an ovoid, slightly yellow soft capsule, containing a whitish oily suspension.

UTROGESTAN 300 mg, soft capsule, soft is an oblong, slightly yellow capsule containing a whitish oily suspension.

UTROGESTAN 400 mg, soft capsule is an oblong, slightly yellow capsule containing a whitish oily suspension.

UTROGESTAN 200 is supplied in blister strips packaged in an outer carton. Each carton contains 7 (trade or starter pack), 14, 15, 21, 28, 30, 42, 45, 56, 84 or 90\* capsules.

UTROGESTAN 300 and UTROGESTAN 400 are supplied in bottles in an outer carton. Each bottle contains 15 or 30 \* capsules.

\* Not all pack sizes may be marketed

AUST R 232824 – Utrogestan 200

AUST R 404350 – Utrogestan 300

AUST R 404382 – Utrogestan 400

### Who distributes UTROGESTAN

Besins Healthcare Australia Pty Ltd  
Level 16, Tower 2, Darling Park,  
201 Sussex Street,  
Sydney NSW 2000

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