

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **UTROGESTAN**[®]

progesterone vaginal soft capsules

This Patient Medication Information is written for the person who will be taking **UTROGESTAN**. This maybe you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **UTROGESTAN**, talk to a healthcare professional.

What **UTROGESTAN** is used for:

UTROGESTAN is used in women undergoing treatment for *in vitro* fertilization (IVF). It is used to support part of the menstrual cycle called the luteal phase.

How **UTROGESTAN** works:

The progesterone in **UTROGESTAN** helps to prepare the lining of the uterus for pregnancy and helps to maintain a pregnancy.

The ingredients in **UTROGESTAN** are:

Medicinal ingredient: progesterone

Non-medicinal ingredients: gelatin, glycerol, purified water, soybean lecithin, sunflower oil, titanium dioxide.

UTROGESTAN comes in the following dosage form:

Soft capsules: 200 mg

Do not use **UTROGESTAN** if you:

- are allergic to progesterone, soybean lecithin, gelatin, peanuts, or any of the other ingredients in **UTROGESTAN** (see **The ingredients in **UTROGESTAN** are:**)
- have severe liver problems or disease
- have abnormal or undiagnosed vaginal bleeding
- are pregnant but the baby has died in your womb (missed abortion) or implantation happened outside of the uterus (ectopic pregnancy)
- have recently had or are having a stroke or a heart attack
- have or have a history of cerebrovascular disease (a condition that affects blood flow to the brain)
- have or have had blood clots in the leg, lungs, eyes, or elsewhere in the body
- have or have had thrombophlebitis (inflammation of the veins)
- have or are suspected to have breast cancer
- have or are suspected to have endometrial, ovarian, cervical or vaginal cancer
- have porphyria (a blood disease)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take UTROGESTAN. Talk about any health conditions or problems you may have, including if you:

- have a history of seizures or epilepsy
- have a history of migraine headaches
- have partial or complete vision loss due to blood vessel disease of the eye
- have asthma
- have heart or kidney problems
- have diabetes
- have a history of depression
- are using other vaginal products, like those used to treat yeast infections
- are older than 35 years of age
- smoke
- have edema (fluid retention)
- are breastfeeding. UTROGESTAN passes into breastmilk.

Other warnings you should know about:

Check-ups and monitoring: Before starting treatment with UTROGESTAN you should have a complete physical exam including examination of your breasts and pelvic organs and a PAP smear. You should see your healthcare professional regularly during treatment.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with UTROGESTAN:

- medicines used to treat Parkinson’s disease, such as selegiline, bromocriptine
- anti-epileptic medicines used to control seizures such as carbamazepine, efavirenz, eslicarbazepine, nevirapine, oxcarbazepine, phenobarbital, phenytoin, primidone, rufinamide
- medicines used to suppress the immune system, such as cyclosporin, tacrolimus
- medicines called “benzodiazepines” used to treat anxiety and sleep problems, such as diazepam, lorazepam
- anticoagulants medicines called “blood thinners” used to prevent the formation of blood clots
- medicines used to treat diabetes
- antifungal medications used to treat fungal infections, such as ketoconazole, itraconazole, fluconazole, voriconazole, griseofulvin
- medicines used to treat HIV, such as darunavir, nelfinavir, fosamprenavir, lopinavir
- medicines used to lower high cholesterol, such as atorvastatin, rosuvastatin
- herbal products containing St John’s wort (*Hypericum perforatum*) used to treat depression
- aprepitant, used to treat nausea and vomiting during chemotherapy
- bosentan, used to treat high blood pressure in the lungs
- rifampicin, an antibiotic medicine used to treat tuberculosis
- spironolactone, a diuretic or “water pill” used to treat heart problems
- tizanidine, a muscle relaxant used to treat multiple sclerosis and other nerve problems
- ulipristal acetate, the emergency birth control pill
- other vaginal products, like those used to treat yeast infections

How to take UTROGESTAN:

- Follow the directions given to you by your healthcare professional.
- You will start taking UTROGESTAN the day of embryo transfer.
- Continue taking UTROGESTAN until your healthcare professional has checked to see if you are pregnant.
- If your healthcare professional has confirmed that you are pregnant, continue taking UTROGESTAN until at least the 7th week of pregnancy but not later than the 12th week of pregnancy.
- Wash your hands before and after inserting UTROGESTAN.
- Insert the UTROGESTAN soft capsule deep into your vagina using your finger.
- Wearing a panty liner is recommended, as sometimes there may be some leakage from the dissolved soft capsule.
- UTROGESTAN is for vaginal use. Do not take it by mouth.

Usual dose:

One UTROGESTAN soft capsule inserted into the vagina three times a day, at morning, lunchtime and bedtime, or as directed by your healthcare professional.

Overdose:

If you think you, or a person you are caring for, have taken too much UTROGESTAN, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you missed a dose of UTROGESTAN insert it as soon as you remember. But if it is almost time for your next dose, skip the missed dose and continue with your next scheduled dose. Go back to the regular dosing schedule. Do not insert two doses at the same time.

Possible side effects from using UTROGESTAN:

These are not all the possible side effects you may have when taking UTROGESTAN. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- abdominal discomfort (distension, pain)
- constipation, diarrhea
- breast tenderness/swelling, pain
- dizziness (lightheadedness)
- fatigue, tiredness
- insomnia, sleepiness
- headache
- rash with or without itching
- swelling

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Common			
Nausea	✓		
Vomiting	✓		
Ovarian Hyperstimulation Syndrome (OHSS): weight gain, bloating or fluid retention in abdomen, nausea, vomiting, pelvic pain		✓	
Vaginal hemorrhage: unusual spotting or bleeding, heavy bleeding that can be sudden or severe, bleeding after intercourse, pain, passing clots		✓	
Uncommon			
Allergic reaction: rash, hives, itchiness, swelling of face, lips or throat, difficulty swallowing or breathing, wheezing, feeling sick to your stomach and throwing up			✓
Vaginal irritation: burning, itching, fatty discharge from the soft capsule	✓		
Stroke (bleeding or blood clot in the brain): sudden severe headache or worsening of headache, vomiting, dizziness, fainting, disturbance of vision or speech, weakness or numbness in an arm or leg			✓
Migraine: severe headache often accompanied by nausea, vomiting and sensitivity to light		✓	
Depression (sad mood that won't go away): difficulty sleeping or sleeping too much, changes in appetite or weight, feelings of worthlessness, guilt, regret, helplessness or hopelessness, withdrawal from social situations, family, gatherings and activities with friends, reduced libido (sex		✓	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
drive) and thoughts of death or suicide. If you have a history of depression, your depression may become worse			
Vaginal yeast infection: itching, burning, soreness, irritation and a whitish-grey cottage cheese-like discharge		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 15- 30°C. Do not refrigerate. Keep out of reach and sight of children.

Do not use UTROGESTAN after the expiry date stated on the packaging. The expiry date refers to the last day of that month.

If you want more information about UTROGESTAN:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); Organon Canada website www.organon.ca or by calling Organon Canada at 1-844-820-5468.

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