

UTROGESTAN ORAL CAPSULE®

Progesterone (100mg)

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What Utrogestan is used for
Utrogestan is used for disorders related to progesterone insufficiency in women:

- Menstrual disorder (irregular or absence of menses)
- Premenstrual syndrome (PMS)
- Menopausal symptoms (used together with estrogen hormone)

How does Utrogestan work

Utrogestan contains natural female hormone progesterone. It is identical to the hormone naturally produced in your body.

As you approach menopause, the amount of female hormones (estrogen and progesterone) in the body drops. Utrogestan when used as prescribed through oral route, restores the level of progesterone in your body and relieves menopausal symptoms.

Before you use Utrogestan

- When you must not use it

Do not use Utrogestan if you are allergic to progesterone or any of the inactive ingredients of this medicine, listed at the end of the leaflet. Signs and symptoms of allergic includes:

- Itchy skin, red rashes
- Swollen lips, tongue, eyes or face
- Feeling tight at your chest, trouble of breathing.

Do not take Utrogestan if you have or have had any of the following conditions:

- if you are allergic to soya
- unusual vaginal bleeding that has not been evaluated by your doctor
- 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)

If any of the above conditions appear for the first time while taking Utrogestan, stop taking it at once and consult your doctor immediately.

Before you start to use it

Talk to your doctor or pharmacist before using Utrogestan.

- Taking other medicines

Please inform your doctor or pharmacist if you are taking or have recently taken or might take any other medicine. This includes medicines obtained without a prescription (from pharmacy, supermarket, convenient shop etc) and any herbal medicines.

How to use Utrogestan

- How to use

Swallow the capsule(s) with a glass of water.

- When to use it

Take after meal, preferably in the evening before going to bed

How much to use, how long to use it

Your doctor or pharmacist will tell you how many capsules you need to take each day.

For women receiving hormone replacement therapy in conjunction with estrogen with an intact uterus (womb), the usual dose is 200 mg/day (2 capsules Utrogestan 100mg a day) at bedtime on days 15 to 26 of your cycle. You will usually have a few days withdrawal bleeding (like a period) after this time. Alternatively 100 mg can be taken at bedtime, from days 1 to 25 of each cycle, withdrawal bleeding being less with this treatment schedule.

For women with secondary amenorrhea (no menstrual periods), the treatment may be taken as a single daily dose of 400 mg (4 capsules Utrogestan 100mg a day) at bedtime, for 10 days.

The standard daily dose is 200 mg (2 capsules Utrogestan 100mg a day) to

300 mg (3 capsules Utrogestan 100mg a day) of progesterone taken in one or two doses (i.e. 200 mg in the evening and another 100 mg in the morning, if needed).

- If you forget to use it

If you forget to take a dose, use as soon as you remember it. However, if it is time for the next dose (in less than 12 hours), skip the missed dose.

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

If you use too much (overdose)

If you take more Utrogestan than you should, stop taking it and talk to your doctor or go to hospital. Take the medicine pack with you.

While you are using it

- Things you must do

Talk to your doctor or pharmacist before taking Utrogestan.

- Things you must not do

Utrogestan is not suitable to be used as contraceptive pill.

Do not give Utrogestan away to others.

- Things to be careful of

Driving and using machines

When taken orally, progesterone may cause drowsiness and/or dizziness, therefore avoid driving or operate machinery after taking Utrogestan. You are advised to take this medicine at bedtime.

Pregnancy, breast-feeding and fertility

Please consult your doctor if you are pregnant or think you are pregnant while you are taking Utrogestan. Talk to your doctor before taking this medicine if you are breast-feeding.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Side effects

Like all medicines, Utrogestan can cause side effects, although not everybody gets them. Occasional side effects include sleepiness and dizziness, shortening of the menstrual cycle or breakthrough bleedings.

If you get any side effects, talk to your doctor or pharmacist. This includes

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any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Consumers ➔ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

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Storage and Disposal of trogestan

- Storage

- Store below 30°C.
- Keep in cool dry place.
Protect from light.
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after expiry date printed on the box.
- Do not use this medicine if you noticed any visible signs of deterioration of the medicine.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use.

Product Description

- How it looks like

Utrogestan is round and a slightly yellow soft capsules, containing whitish oily suspension. These are packed in blisters inside a box.
Blister: Aluminium foil/ PVC blister pack with an outer carton; 30 capsules.

- Ingredients

Active Ingredient:
Micronized
progesterone.

Inactive ingredients:

Sunflower oil, soybean lecithin, gelatin, glycerol and titanium dioxide.

- MAL Number

MAL19971796ACRZ

Manufacturers

Cyndeia Pharma S.L.
Poligono Industrial Emiliano Revilla
Sanz, Avenida de Agreda, 31-42110
Olvega, (Soria), Spain

Product Registration Holder

EP Plus Group Sdn. Bhd.