

Utrogestan 100mg Capsules Progesterone

INFORMATION FOR THE PATIENT UTROGESTAN 100mg CAPSULES Progesterone

Please read this leaflet carefully BEFORE you take your Utrogestan 100mg Capsules. This leaflet is a summary of the important information about your capsules. Keep it in a safe place, you may want to refer to it again. If you have any questions or are not sure about anything to do with your treatment, ask your doctor or pharmacist for more information.

What is in your medicine?

Each Utrogestan 100mg soft capsule contains 100mg of progesterone as the active ingredient.

Utrogestan 100mg Capsules are soft white capsules and also contain the following ingredients: Arachis Oil (peanut oil), Soya Bean Lecithin, Gelatin, Glycerol and Titanium Dioxide.

Glycerol in high doses may cause headache and can also cause stomach upset and diarrhoea.

Due to the peanut oil and soy lecithin in the composition, there is a risk of unexpected hypersensitivity reactions (anaphylactic shock, hives).

Utrogestan 100mg Capsules are available in packs of 30 capsules each. They are supplied in packs of three blisters containing 30 soft white capsules.

What you should know about Utrogestan 100mg Capsules.

The company responsible (also known as the Marketing Authorisation Holder) for this product is Besins Healthcare SA, Rue Vilian XIII, n19, 1000 Brussels, Belgium.

The product is made by Besins Manufacturing Belgium, S.A., Groot-Bijgaardenstraat 128, 1620 Drogenbos, Belgium and Laboratoires Besins International, S.A, 13 Rue Perier- BP 41, 92122 Montrouge Cedex, France.

What are Utrogestan 100mg Capsules for?

Utrogestan when used as prescribed, restores the level of progesterone in your body so that it is similar to the level that existed before your menopause. This 'hormone replacement therapy' or HRT prevents or relieves the related symptoms you may have been experiencing. Utrogestan is not a contraceptive, nor will it restore fertility. If you are using contraceptives please consult your doctor before starting treatment with Utrogestan

If you need any further information please ask your doctor.

Before taking your capsules

Do not use Utrogestan if

- you are hypersensitive to any of the ingredients (see list of ingredients above).
- you suffer from severe disturbances of the liver function (including porphyria), or have had previous or existing liver tumours
- you suffer from serious kidney or heart disease.
- you are receiving treatment or you have been treated for any kind of blood problem, such as blood clots.
- you have had some bleeding since your last period, or between periods if these are still regular.
- you have endometriosis (where the cells lining of the uterus are found in other parts of the body).
- you are pregnant, planning a pregnancy, or suspect you could be pregnant?
- you are breast-feeding?
- you have suffered from jaundice or general pruritus (skin rash) during a previous pregnancy.
- you have suffered from otosclerosis (ear disorder) with deterioration in previous pregnancies
- you suffer from active deep venous thrombosis or from thromboembolic disorders or have had a past history of these conditions.
- you suffer from disturbances of lipid metabolism.
- you have a history of herpes gestations
- you suffer from sickle cell anaemia.
- you suffer from suspected existing hormone dependent disorders or tumours of the uterus, breast or ovaries.
- you suffer from Rotor syndrome or Dubin-Johnson syndrome
- you suffer from severe diabetes with vascular changes

Consult your doctor before using Utrogestan if:

- you have not had a complete physical and gynaecological examination
- you suffer from epilepsy, multiple sclerosis, migraines, asthma, high blood pressure, heart or kidney problems, varicose veins or diabetes.
- you have breast pain or a strong family history of breast cancer.
- you are due to have an operation in the near future as you may be advised to temporarily stop using UTROGESTAN 4 weeks earlier.
- you are bed-ridden for a long period of time as you may be advised to temporarily stop using UTROGESTAN.
- you have an allergy to peanuts.

Use with other medicines.

It is important to tell your doctor about all the medicines you are taking including any you have bought without prescription. In particular, tell your doctor if you are taking anticonvulsants (to help prevent fits), barbiturates (a type of sedative), antibiotics or activated charcoal.

If you have to go to a doctor, dentist or hospital for any reason, tell them that you are taking Utrogestan 100mg Capsules.

Special Warnings

- Do not exceed the prescribed dose, If the prescribed dose does not provide adequate relief of symptoms consult your doctor.
- While you are receiving this medication, you should see a doctor regularly, at least twice a year.
- Patients with a family history of breast cancer should use the medication with great caution.
- If you have any unusual symptoms such as unexplained pains in the chest, abdomen or legs you must consult your doctor immediately.
- Patients with a history of thromboembolic disorder (the development of blood clots in the veins) should use the medication with caution.
- Treatment should be stopped immediately if the following occur. you experience a migraine or frequent and unusually severe headaches occur for the first time or sudden visual disturbances; you develop liver problems (jaundice, cholestasis, hepatitis); you become pregnant or if your blood pressure rises significantly or you have an increase in epileptic seizures.
- If you experience any irregular bleeding while using Utrogestan consult your doctor,
- If you experience drowsiness while using Utrogestan do not drive or operate machinery.

Taking your capsules

The usual total daily dose is 300mg in divided doses (200mg at night before retiring and 100mg in the morning) for ten to fourteen consecutive days. Utrogestan should be administered concurrently with oestrogen therapy during the last 10 to 14 days of each cycle of such treatment.

If you forget to take your Utrogestan 100mg Capsules.

Do not worry. You can take them as soon as you remember. Under NO circumstances take double the dose on the same day.

If you have swallowed too much or if a child has swallowed any of your tablets, contact your nearest hospital casualty department or tell your doctor IMMEDIATELY.

After taking your capsules

As well as benefits, all medicines may occasionally have some unwanted effects in some patients.

These are called side effects:

During the first few months of treatment, breakthrough bleeding, spotting and breast tenderness or enlargement can occur. These are usually temporary and normally disappear after continued treatment.

The most frequently reported adverse reactions are: skin disorders including pruritus, gastrointestinal disorders (including nausea, abdominal pain and bloating), liver disorders, cardiac disorders and reproductive disorders.

Other symptoms known to occur are: headache; migraine; drowsiness, dizziness, anxiety/depressive symptoms; alterations in body weight, oedema; hypertension; altered libido, changes in vaginal secretion, growth of pre-existing fibroids, chloasma or melasma (discolouration of the skin) which may be persistent. Some women are predisposed to cholestasis during steroid therapy.

Due to the peanut oil and soy lecithin in the composition, there is a risk of unexpected hypersensitivity reactions (anaphylactic shock, hives).

Do not be alarmed by this list of side effects. You do not need to worry about them unless they become troublesome in which case contact your doctor.

If you notice any other changes in your health whilst taking medicine, **tell your doctor immediately.**

Expiry Date

You must not take Utrogestan after the expiry date. This is given in the following place.

- on the blister
- on the box.

It is given as EXP followed by the month and year. The medicine should not be used after the end of that month. If you are not sure when this is check with your doctor or pharmacist.

Storing your medicine

Do not store above 25°C. Keep the blister in the outer carton in order to protect from light.

Keep your tablets in a safe place and out of the reach and sight of children.

Do not keep your tablets if your doctor decides to stop treatment. Return them to your pharmacist who will arrange for their destruction.

Remember: these capsules are only for you. Only a doctor may prescribe them for you. Never give your medicines to other people. They may harm other people even if their symptoms are the same as yours.

This leaflet was written in August 2007.