UTROGESTAN 100 mg capsules, soft
Progesterone

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT UTROGESTAN IS AND WHAT IT IS USED FOR

Utrogestan is a hormone product that contains progesterone. This drug is prescribed for disorders related to a progesterone deficit:

**Oral route**
- pre-menstrual disorders
- menstrual irregularity due to ovulation disorder or dysovulation
- benign mastopathy
- premenopause
- therapy of the menopause (in complement to estrogen therapy).

**Vaginal route**
Vaginal route is alternative to the oral route.
1) Particularly it is indicated for following:
- Progesterone support during ovarian insufficiency or complete ovarian failure in women lacking ovarian function (oocyte donation);
- Luteal phase supplementation during in vitro fertilization cycles;
- Luteal phase supplementation during spontaneous or induced cycles, in primary or secondary sterility or subfertility in particular due to dysovulation;
- Threatened miscarriage or prevention of habitual miscarriage due to luteal phase deficiency up until the 12th week of pregnancy.

2) For all other progesterone indications, the vaginal route provides an alternative to the oral route in cases of:
- Undesirable effects of progesterone (drowsiness)
- Contraindication for absorption by the oral route (liver disease).
2. BEFORE YOU TAKE UTROGESTAN

Do not use UTROGESTAN
- Attention! If you suffer from a liver disease or if you have a hepatic function disorder you should not use Utrogestan via oral route
- Utrogestan should not be used in case of known hypersensitivity to any of the substances of the medical product
If you are not sure, please always ask you doctor or pharmacist!

Take special care with Utrogestan
- Utrogestan is not a treatment of each case of spontaneous premature abortions. In particular this medicine has no effect on those induced by genetic complications (more than half).
- Utrogestan should only be used in pregnancy during the first trimester and only by the vaginal route. There is some risks of undesirable effects if the medicine is used during the second and third trimesters of pregnancy.
- The treatment, in the recommended conditions of use, is not contraceptive.
- For oral rout, it is recommended to use the medicine far from mealtimes
- Vaginal route: Patients must insert each capsule at the back of the vagina

Using other medicines
In order to avoid possible interaction with other medicinal products please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding
Many epidemiological studies on more than a thousand patients have not revealed any association between Utrogestan and foetal malformations. Progesterone can pass through the placenta and is excreted in the milk. Use of Utrogestan during breast-feeding is not recommended. In case of pregnancy and breast-feeding always ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
As in rare cases Utrogesatn may cause drowsiness or dizziness, caution should be exercised with driving or using machines.

Important information about some of the ingredients of Utrogestan
Utrogestan capsules contain peanut oil. It is recommended that you do not use Utrogestan if you have a peanut or soya allergy.

3. HOW TO USE UTROGESTAN

Always use Utrogestan exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
If your therapist did not prescribe you a specific dosage schedule, the usual dose is:

On average for progesterone insufficiencies, the daily dose is 200 to 300 mg (2 or 3 capsules) divided in two intakes: 1 capsule in the morning, and 1 or 2 capsules at bedtime. In some cases, notably to help pregnancy, your doctor can increase the dosage to 600 mg per day in three divided doses.

In all cases, the dose must not exceed 200 mg per intake.

If you have the impression that the effect of Utrogestan is too strong or too weak, talk to your doctor or pharmacist.
The treatment may be prescribed continuously or by sequences of few days per month, more or less associated with an oestrogen therapy.

Two routes of administration are possible for Utrogestan – an oral route and a vaginal route. It will be decided on an individual basis by your doctor.
• If the drug is to be administered orally, swallow the capsule with a glass of water far from mealtimes, according to your doctor prescription.
• If the drug is to be administered vaginally, insert each capsule deeply in the vagina.

Duration of treatment will be specified by your doctor, according to indications. Depending on the nature of indication and therapeutic efficacy, your doctor may re-adjust the duration of treatment.

If you use more Utrogestan than you should
In case you use more Utrogestan than you should please talk to a doctor or pharmacist immediately

If you forget to use Utrogestan or if you use less Utrogestan that you should
Do not take a double dose to make up for forgotten individual doses.

If you stop using Utrogestan
No adverse effects are observed after discontinuation of treatment.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Utrogestan can cause side effects, although not everybody gets them.

After oral route of administration, the following side effects have been reported:
• drowsiness or dizziness can occur 1 to 3 hours after Utrogestan intake.
• menstrual irregularities, intra menstrual bleeding.

These events generally occur as a consequence of overdosing.

In these cases, it is recommended that:
• Reduce the dosage per dose,
• change the dosing schedule (for example, for a dosage of 200 mg/day, take the 200 mg in the evening on an empty stomach before going to bed)
• the regimen of administrations should be changed to a vaginal route

In all cases, the dose must not exceed 200 mg per intake.

If overdosing symptoms have been observed, consult your doctor who can adapt the treatment according to your individual needs.

Due to the peanut oil (arachis oil) and soy lecithin, there is a risk of allergic reactions.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE UTROGESTAN

Do not store above 25°C. Store in a dry place, protected from light.

Keep out of the reach and sight of children.
Do not use Utrogestan after the expiry date which is stated on the package or if you notice visible signs of deterioration. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Utrogestan contains
Each soft capsule contains:
Active substance: 100 mg micronised progesterone
The other ingredients are: arachis oil, soya bean lecithin, gelatine, glycerine and titanium dioxide.

What Utrogestan looks like and contents of the pack
Carton box with 2 blisters containing 15 soft capsules.

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