

Package leaflet: information for the patient  
Utrogestan 100 mg, Capsules  
progesterone

Read the entire leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

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## 1. What is Utrogestan and what is it used for?

What is Utrogestan?

Progesterone is a natural hormone that can be prescribed as a supplement to estrogen therapy during or after menopause. It can also be prescribed when there is a progesterone deficiency, such as in certain menstrual cycle disorders.

What is the medicine used for?

The active substance of Utrogestan is progesterone, a natural female hormone. In healthy women of childbearing age, progesterone is produced every month in the second half of the cycle by the ovaries.

Progesterone plays a role, among other things, in the monthly shedding of the uterine lining and the subsequent menstruation. Together with other hormones, it is indispensable for establishing a normal, regular menstrual cycle.

Utrogestan can be used as a supplement to estrogen therapy during menopause and the period thereafter. It prevents the uterine lining from being overly stimulated by estrogens, thereby reducing the risk of uterine cancer. A few days after ending a course of Utrogestan, the uterine lining may shed. This can (just like with a regular menstruation) be accompanied by bleeding.

In case of a progesterone deficiency, such as with certain menstrual cycle disorders, Utrogestan can help supplement this deficiency.

## 2. When should you not take this medicine or be extra careful with it?

When should you not use this medicine?

Do not use if:

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6 of this leaflet.  
severe liver disorders, such as jaundice, liver inflammation (hepatitis), a liver tumor, or the rare liver diseases Rotor syndrome and Dubin-Johnson syndrome. Also not if the liver has not fully recovered after such a severe condition;  
unexpected vaginal bleeding;  
certain conditions that occurred or worsened during pregnancy or previous hormone use; namely: jaundice, severe itching, skin rash in the form of blisters (herpes gestationis), a metabolic liver disease (porphyria), or a hereditary form of deafness (otosclerosis).

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before taking this medicine.

Extra monitoring by your doctor may be necessary in some cases. Therefore, you should inform the doctor if you have or have had any of the following conditions:

liver disorder, such as jaundice;  
"pregnancy spots" (patchy skin discoloration) - exposure to natural or artificial sunlight should be avoided;  
cardiovascular disease, although there is no evidence of an increased risk with Utrogestan.

Are you taking any other medicines?

Other medicines can affect the action of Utrogestan. Therefore, tell the doctor if you are using or going to use any of the following medicines:

barbiturates (medications for epilepsy or sleep disorders);  
carbamazepine (medication for epilepsy);  
cyclosporin (used after a transplant);  
activated charcoal (e.g., Norit);  
griseofulvin (medication for fungal infections);  
hydantoin derivatives (medications for epilepsy);  
rifampicin (medication for bacterial infections);  
theophylline (medication for asthma);  
troleandomycin (medication for asthma).

Pregnancy, breastfeeding, and fertility

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Driving ability and the use of machines.

Utrogestan may cause drowsiness or dizziness. Therefore, be careful when driving and other activities that require constant attention.

Utrogestan contains soy lecithin (E322)

Do not use this medicine if you are allergic to peanuts and soy.

### 3. How to take this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

**Dosage.** The usual dosage is 200 or 300 mg progesterone (2 or 3 capsules) per day for 12-14 days per month. For a dosage of 300 mg per day, take one capsule in the morning and two capsules in the evening before bedtime. For 200 mg per day, the total daily dosage (2 capsules) should be taken before bedtime.

**How to take.** Swallow the capsules without chewing with, for example, half a glass of water. Do this at the same time each day.

**What if you forget a dose.** If you are being treated with 3 capsules per day and you forget a morning or evening dose, you should not take the missed dose and continue taking the rest of the capsules as usual. However, if you are being treated with 2 capsules per day (total dose at bedtime) and you forget a dose, you should take one capsule the next morning and then continue as usual with two capsules at bedtime.

**Have you taken too much of this medicine?**

In the case of a one-time overdose (for example, if a child has taken several capsules), there is no reason for great concern. Nevertheless, you should consult a doctor in that case. Symptoms that may occur include: nausea, vomiting, drowsiness, and dizziness.

**Have you forgotten to use this medicine?**

If you forget a dose, administer it as soon as possible. But if it is almost time for the next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten dose.

#### 4. Possible side effects

Like any medicine, this medicine can have side effects. Not everyone will experience them.

Utrogestan can, depending on the dosage and the sensitivity of the patient, cause the following side effects:

- vaginal bleeding (outside the normal monthly period);
- irregular menstrual cycle;
- tender breasts;
- nausea
- dizziness;
- drowsiness;
- fatigue;
- headache or migraine

Further side effects attributed to progestogens (substances similar to progesterone) that may also occur during treatment with Utrogestan are:

- stomach or intestinal complaints (other than nausea);
- "pregnancy spots" (patchy skin discoloration);
- itching;
- skin rash;

jaundice;  
depressive mood;  
increase or decrease in libido;  
absence of the monthly bleeding.

If you experience these side effects, you should contact your doctor, especially in case of unusual vaginal bleeding.

#### Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: [www.lareb.nl](http://www.lareb.nl). By reporting side effects, you can help us obtain more information about the safety of this medicine.

#### 5. How to store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find it on the packaging after 'Exp.'. It includes a month and a year. The last day of that month is the expiry date.

Store below 30°C. Do not store in the refrigerator. Store in the original packaging to protect from light.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed correctly and do not enter the environment.

#### 6. Contents of the packaging and other information

What substances are in this medicine?

- The active substance in this medicine is progesterone. It is present in micronized form in a soft capsule 100 mg.
- The other ingredients in this medicine are soy lecithin (E322) and sunflower oil. The capsule itself is made of gelatin, glycerol, and titanium dioxide (E171).

What does Utrogestan look like and what is in a package?

Utrogestan 100 mg: box with 30 soft capsules (in blisterpacks) for oral use

Utrogestan 100 mg are round, light yellow capsules

#### Marketing authorization holder and manufacturer

Marketing authorization holder

Besins Healthcare Netherlands BV,

Servaasbolwerk 14,

3512NK Utrecht,

Netherlands

Manufacturer

Cyndea Pharma S.L.

Polígono Industrial Emiliano Revilla Sanz

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or

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Polígono Industrial El Pitarco, plot no. 4  
50450 Muel (Zaragoza)  
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Registered under RVG 11473

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