You have received this brochure
from your doctor/nurse

PATIENT INFORMATION

Treatment with

Utrogestan®

(micronised progesterone)

– in combination with
estrogen in menopause

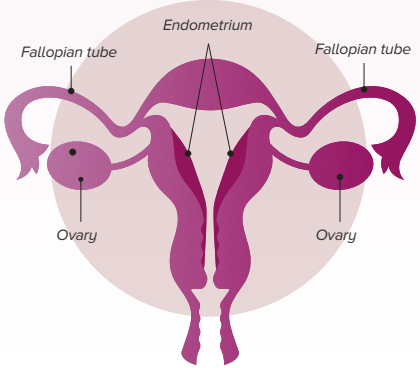
Hormon replacement therapy with bioidentical progesterone; is used together with estrogen to reduce the symptoms of the menopause

Why is progesterone taken with estrogen?

You have been prescribed estrogen to relieve your menopausal symptoms. Utrogestan® is used as an addition to estrogen hormone therapy in menopausal women with an intact uterus. Estrogen can affect the lining of the uterus, causing it to grow and thicken. A thickened lining can cause problems with, so called, breakthrough bleeding. Progesterone counteracts this.

When prescribed estrogen therapy, it is recommended that progesterone is added. If not, there may be an increased risk of developing uterine cancer in the long term.

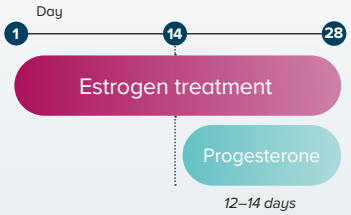
Progesterone counteracts the unwanted growth of the endometrium that can occur with estrogen therapy.



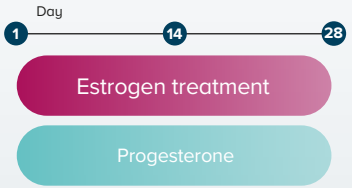
Reference: 1177.se

Sequential or continuous treatment

Progesterone treatment can be given in two ways: *sequential treatment* is given to women who are still menstruating and involves taking progesterone for 12–14 days per month. The other way is *continuous treatment,* which means taking progesterone daily. This treatment requires that the woman is past the menopause and has not had a period in the last year.



Sequential treatment
Mimics the natural menstrual cycle.



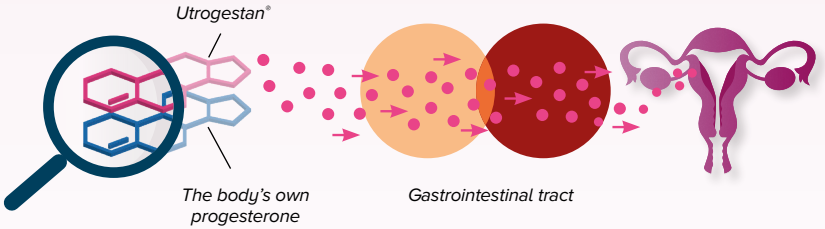
Continuous treatment
A treatment without bleeding – at the earliest one year after the last menstruation.

What is **Utrogestan®**?

Utrogestan® contains a bioidentical micronised progesterone used as a hormone replacement therapy (HRT), in combination with estrogen, during and after menopause.

Bioidentical means that Utrogestan® contains a progesterone that is designed to be identical to the progesterone your body produces.

Micronised means that the progesterone is composed of very small molecules in a vegetable oil solution, which facilitates its passage through the gastrointestinal tract into the bloodstream and to the endometrium.



Utrogestan® has an identical composition to the progesterone your body produces.

How to use Utrogestan®

Utrogestan® is a prescription medicine available as 100 mg and 200 mg capsules. It is a round, yellowish, soft gelatin capsule containing a whitish paste. The capsules should be swallowed whole with some water. Do not take the capsules with food.

The recommended dose is 200 mg every night at bedtime, for at least 12–14 days at the end of each treatment cycle.

Always take the medicine as prescribed by your doctor.

Your doctor's prescription:

Important

Utrogestan® contains soy lecithin. If you are allergic to peanuts or soy, do not use this medicine.

If you take more Utrogestan® than you should

If you have taken too much Utrogestan® or if a child has accidentally ingested the medicine, contact a doctor, hospital or call the Poisons Information Centre, telephone number: 112. Symptoms of an overdose include dizziness, tiredness, intense feelings of well-being or painful menstruation. If you experience these symptoms, the dose can be reduced. Always ask your doctor before changing the dose.

If you forgot to take Utrogestan®

If you have missed a dose, take it as soon as you remember. Do not take a double dose to make up for a missed dose.

Driving and using machines

Utrogestan® may cause drowsiness and/or dizziness. You are responsible for assessing whether you can drive or perform work that requires close attention.

Utrogestan® and other medicines

Some medicines can affect the effect of Utrogestan®, so always talk to your doctor or pharmacist if you are taking – or have recently taken – any other medicines (including over-the-counter medicines).

Special precautions for storage

Like all medicines, Utrogestan® should be stored safely and out of the reach of children. Store at a maximum of 30 °C. Do not freeze.

Package leaflet

Always follow your doctor's prescription and read the instructions in the package leaflet carefully.

Side effects and selected safety information

Like all medicines, this medicine may cause side effects, but not all users will experience them.

Common side effects (may affect up to 1 in 10 people): Headache and changes in menstrual flow, or bleeding at times other than the withdrawal period. Less common side effects (may affect up to 1 in 100 people): Changes in the breasts or breast tenderness, fatigue, dizziness, vomiting, diarrhoea, constipation, yellowing of the skin or whites of the eyes (jaundice). Itchy skin, acne.

Rare side effects (may occur in up to 1 in 1,000 people): Allergic reactions and nausea.

Very rare side effects (may occur in up to 1 in 10,000 people): Depression, rash, dark pigmented skin (melasma).

Warnings and precautions:

- When used as recommended, this medicine is not a contraceptive.
- Before starting hormone therapy during menopause (and regularly every year thereafter), you should have a clinical examination of the breasts and pelvis.
- If treatment with Utrogestan® is started too early in the month, especially before the 15th day of the cycle, the cycle may be shortened or bleeding may occur.

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Do not take Utrogestan®:

- If you are allergic to progesterone or any of the other ingredients of this medicine.
- If you have unexplained bleeding from the lower abdomen.
- If you have severe liver problems.
- If you have a liver tumor.
- If you have or may have tumors in your breasts or genitals.
- If you have an active blood clot in a vein (thrombosis), for example in your legs (deep vein thrombosis) or in your lungs (pulmonary embolism) or if you have a history of these types of blood clots.
- If you have bleeding in or around the brain (cerebral haemorrhage)
- If you have a rare hereditary disease called porphyria.
- If you are using Utrogestan® during the menopause in combination with another hormone therapy, i.e. estrogen, you should also read the package leaflet for that medicine for information on when not to use this medicine.

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