PACKAGE LEAFLET: INFORMATION FOR THE USER

UTROGESTAN 100 mg soft capsules
UTROGESTAN 200 mg soft capsules

Micronised progesterone

Read all of this 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.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. WHAT **UTROGESTAN soft capsules** IS AND WHAT IT IS USED FOR

• Pharmacotherapeutic group

NATURAL PROGESTERONE for oral use belonging to the PROGESTIN group.

• Therapeutic indications

In gynaecology:

- This medicine can be used to correct problems that may occur in the period preceding the onset of menstrual periods (premenstrual syndrome); these problems are present at the same time or separately:
- unpleasant breast tenderness (mastodynia).
- sensation of swollen stomach or legs.
- sensation of heavy legs or excessive tiredness.
- mood changes, increased nervousness or aggressiveness.

- Similarly, it may be indicated when periods do not regularly appear each month. In this case, the problems listed above may appear; these problems appear more frequently in women approaching 50 years of age at the time when periods become irregular.

- **UTROGESTAN soft capsules** is indicated to treat certain benign diseases of the breast (mastopathy). These may be discovered during a self-examination of the breasts. This examination should be carried out by the woman herself, outside the period preceding her period, as recommended by a doctor.

- When periods have no longer appeared spontaneously for at least one year - i.e. when menopause has set in - **UTROGESTAN soft capsules** is indicated and recommended in cases where the doctor prescribes hormonal treatment with oestrogens. In this way, the woman will fully benefit from her oestrogen treatment without experiencing its drawbacks.

- **UTROGESTAN soft capsules** is also indicated in the treatment of certain forms of infertility in women unable to produce enough hormones to become pregnant.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE **UTROGESTAN soft capsules**

Do not take UTROGESTAN:
- if your liver function is severely impaired;
- if you have a neoplasm (tumour) of the breast or genital organs, suspected or confirmed; - if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6).

UTROGESTAN soft capsules increases the amount of progesterone in the blood without formation of non-natural derivatives.

Warnings and precautions

Take special care with UTROGESTAN, as this treatment, under the recommended conditions of use, **does not prevent pregnancy and is therefore not contraceptive**.

If the treatment schedule is started too early in the month, especially before day 15 of the cycle, this may shorten the cycle or bleeding may occur.

More than half of spontaneous abortions are due to genetic complications. Furthermore, infections and mechanical disorders may be responsible for miscarriages; in which case, the sole effect of administering progesterone would be a delay in the expulsion of a dead egg. Progesterone administration must therefore only be reserved for cases where progesterone secretion is insufficient, as recommended by a doctor.

Please consult your doctor if any of the above-mentioned warnings apply to you, or have done so in the past.

Other medicines and UTROGESTAN soft capsules

During HRT with oestrogens, progesterone administration for a minimum of 10 years per cycle is strongly recommended or even essential, so that the patient will get the maximum benefit from her oestrogen treatment.

Certain medicines for epilepsy and some antibiotics may have an influence on the effect of Utrogestan. Similarly, Utrogestan may affect medicines used in diabetes. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

UTROGESTAN soft capsules with food and drink

Smoking may reduce the bioavailability of progesterone and alcohol abuse may increase it.

Pregnancy

The use of **UTROGESTAN soft capsules** is not contraindicated during pregnancy, including during the first few weeks.

UTROGESTAN soft capsules may be indicated with a view to preventing repeated miscarriages, or for repeated contractions which might induce premature birth, as recommended by a doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding

The passage of progesterone into milk has not been studied in detail. Progesterone should preferably not be taken during the breast-feeding period.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

If you are affected by drowsiness or dizziness, do not drive and/or use machines.

UTROGESTAN soft capsules contains soya

If you are allergic to soya, you are advised not to take this medicine.

3. HOW TO TAKE **UTROGESTAN soft capsules**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Take one 200 mg capsule or two 100 mg capsules **in the evening AT BEDTIME** and one 100 mg capsule **in the morning if necessary**. (The total daily dose is 200 to 300 mg progesterone). Take the capsules by swallowing them with a little water.

- **To correct problems that may occur in the period preceding the onset of periods** (premenstrual syndrome, irregular periods, just before the menopause, benign breast diseases): treatment is used for **10 days** per cycle, usually from days **17 to 26** of the cycle inclusive.
- **In the treatment of established menopause (see therapeutic indications)**, it is not recommended to take oestrogens on their own, so the patient should, for example, take UTROGESTAN (two 100 mg capsules or one 200 mg capsule per day) during the last 2 of the 3 weeks when she is taking oestrogens; she should stop taking UTROGESTAN and oestrogens for 1 week out of 4. During this one-week break, so-called withdrawal bleeding may occur.
- **To prevent miscarriage or premature birth, or in the event of such a threat:** 300 mg to 400 mg progesterone, to be taken every 6 to 8 hours, depending on the clinical results obtained in the acute phase, followed by maintenance treatment up to week 36 of pregnancy.

If no improvement occurs, please consult your doctor.

Your doctor will tell you how long to use **UTROGESTAN soft capsules**. Do not stop your treatment too soon.

Use in children:

The efficacy and safety of UTROGESTAN in children have not been established.

If you take more UTROGESTAN soft capsules than you should:

More often than not, undesirable effects are signs of an overdose. They disappear spontaneously when the dosage is reduced, or by increasing the daily dose of concomitant oestrogen in menopause treatment.

In some people, the usual dosage may prove too high, due to particular sensitivities that may occur. In such cases:
- if drowsiness or temporary dizziness occurs, the dose should be reduced or progesterone should be taken in the evening at bedtime, for 10 days per cycle.
- if the cycle is shortened or if irregular bleeding occurs, the start of treatment should be delayed until later on in the cycle (for example, on day 19 instead of day 17).

If you take more **UTROGESTAN soft capsules** than you should, contact your doctor, pharmacist or the Anti-Poisons Centre immediately (070/245.245).

If you forget to take UTROGESTAN soft capsules:

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

If you stop taking UTROGESTAN soft capsules:

Not applicable.

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

4. POSSIBLE SIDE EFFECTS

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

The following table lists the side effects by frequency.

System organ class	Common side effects ≥1/100; <1/10	Uncommon side effects ≥1/1,000; ≤1/100	Rare side effects ≥1/10,000; ≤1/1,000	Very rare side effects ≤1/10,000
Reproductive system and breast disorders	. Altered menstrual cycles . Absent periods . Bleeding between periods	. Painful breasts		
Nervous system disorders	. Headache	. Drowsiness . Temporary dizziness		. Depression
Gastrointestinal disorders		. Vomiting . Diarrhoea . Constipation	. Nausea	
Hepatobiliary disorders		. Cholestatic jaundice		
Immune system disorders				. Hives
Skin and subcutaneous tissue disorders		. Itching . Acne		. Chloasma

If the treatment schedule is started too early in the month, especially before day 15 of the cycle, this may shorten the cycle or bleeding may occur.
Furthermore, if the dose of medicine taken is too high, drowsiness or dizziness may be observed; this effect can be reversed by reducing the dosage, without compromising the benefit of treatment.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

Belgium:
Agence fédérale des médicaments et des produits de santé (Federal Agency for Medicines and Health Products), website: www.afmps.be; e-mail: patientinfo@fagg-afmps.be Luxembourg:

Direction de la Santé – Division de la Pharmacie et des Médicaments (Health Directorate - Pharmacy and Medicines Division), website:
http://www.ms.public.lu/fr/activites/pharmacie-medicament/index.html

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE **UTROGESTAN soft capsules**

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions. Store in the original package.

Do not use this medicine after the expiry date which is stated on the box after "EXP". The expiry date refers to the last day of that month.

Do not use this medicine if you notice any visible signs of deterioration of the product.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you do not use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What UTROGESTAN contains

The active substance is progesterone. It is supplied in micronised form, equivalent to 100 mg or 200 mg per soft capsule.

UTROGESTAN 100 mg soft capsules contains 100 mg progesterone per capsule. UTROGESTAN 200 mg soft capsules contains 200 mg progesterone per capsule.

The other ingredients (excipients) are the same for both dosages: soya lecithin - sunflower oil - titanium oxide - gelatin - glycerol - purified water q.s.p. 1 capsule.

What UTROGESTAN looks like and contents of the pack:

UTROGESTAN 100 mg soft capsules is supplied in boxes of **10, 30** or **90** soft capsules for oral use and packed in blisters.

UTROGESTAN 200 mg soft capsules is supplied in boxes of **15** or **45** soft capsules for oral use and packed in blisters.

Marketing Authorisation Holder:

BESINS HEALTHCARE BENELUX
Avenue Louise, 287
1050 Brussels

Belgium

Manufacturers

Besins Manufacturing Belgium S.A.
Groot-Bijgaardenstraat, 128
1620 Drogenbos
Belgium

Or

CYNDEA PHARMA S.L.
Polígono Industrial Emiliano Revilla Sanz
Avenida de Ágreda, 31,
Olvega 42110 (Soria)
Spain

Marketing Authorisation Number

UTROGESTAN 100 mg soft capsules: BE 117923
UTROGESTAN 200 mg soft capsules: BE 279386

Contact your doctor or pharmacist for any information relating to this medicine.

For any further information on this medicine, please contact the marketing authorisation holder:

BESINS HEALTHCARE BENELUX
Avenue Louise, 287
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Medicinal product subject to medical prescription.

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