

PACKAGE LEAFLET: INFORMATION FOR THE USER

**UTROGESTAN VAGINAL 100 mg soft capsules**  
**UTROGESTAN VAGINAL 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 VAGINAL soft capsules** is and what it is used for
2. What you need to know before you take **UTROGESTAN VAGINAL soft capsules**
3. How to take **UTROGESTAN VAGINAL soft capsules**
4. Possible side effects
5. How to store **UTROGESTAN VAGINAL soft capsules**
6. Contents of the pack and other information

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

**• Pharmacotherapeutic group**

NATURAL PROGESTERONE for vaginal use belonging to the PROGESTIN group.

**• Therapeutic indications**

**UTROGESTAN VAGINAL soft capsules** is indicated in the treatment of certain forms of subfertility or primary/secondary infertility in women unable to produce enough progesterone to become pregnant or to maintain a pregnancy, especially in IVF programmes and/or egg donations.

In pregnant women:

**UTROGESTAN VAGINAL soft capsules** may be indicated with a view to preventing repeated miscarriages or avoiding miscarriages caused by insufficient production of progesterone.

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

**Do not take** UTROGESTAN VAGINAL:

- 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).

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

### **Warnings and precautions**

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

No changes in coagulation have been found in terms of excessive blood clotting. Furthermore, **UTROGESTAN VAGINAL** does not exert any effect which might lead to an increase in blood pressure.

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.

**The woman must insert each capsule deep into the vagina.**

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 VAGINAL soft capsules**

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 VAGINAL soft capsules with food and drink**

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

### **Pregnancy**

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

**UTROGESTAN VAGINAL 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 VAGINAL soft capsules contains soya**

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

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

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

Insert one 100 mg capsule in the morning and one 100 mg capsule in the evening, deep into the vagina, using an applicator if necessary (the total dose is 2 capsules per day, i.e. 200 mg per day). The dosage can be increased depending on the patient's response.

- In the treatment of infertility due to totally inadequate progesterone production (egg donations), the usual dosage is one 100 mg capsule per day on days 13 and 14 of the transfer cycle, then one 100 mg capsule on the morning and evening of days 15 to 25 of the cycle. From day 26, if pregnancy has started, the dose is increased by 100 mg/day every week, reaching a maximum of 600 mg/day, spread over 3 doses. This dosage is maintained until day 60.
- For supplementation of the second part of the cycle in IVF programmes, the recommended

treatment is 600 mg/day, spread over 3 doses, morning, noon and evening, starting from the day of the transfer.

- Supplementation of the luteal phase in spontaneous or induced cycles, in cases of subfertility or primary/secondary infertility, especially due to poor ovulation: the recommended dosage is 200 mg/day, starting from day 17 of the cycle, for 10 days.
- For threatened miscarriage or to prevent repeated miscarriages due to a lack of progesterone, the recommended dosage is 200 to 400 mg/day in two doses. If periods fail to return and pregnancy is confirmed, this dosage is maintained up until week 12 of pregnancy.

If no improvement occurs, please consult your doctor.

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

**Use in children:**

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

**If you take more UTROGESTAN VAGINAL soft capsules than you should:**

No overdose has been reported to date with this route of administration.

Undesirable effects have been observed when UTROGESTAN is taken **orally** and are most often the sign 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 VAGINAL soft capsules than you should, contact your doctor, pharmacist or the Anti-Poisons Centre immediately (070/245.245).

**If you forget to take UTROGESTAN VAGINAL soft capsules:**

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

**If you stop taking UTROGESTAN VAGINAL 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.

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.

No significant local intolerance (burning, itching or greasy discharge) has been observed during the various studies.

The following effects have been observed **with the oral route**:

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
<b>Reproductive system and breast disorders</b>	. Altered menstrual cycles . Absent periods . Bleeding between periods	. Painful breasts		
<b>Nervous system disorders</b>	. Headache	. Drowsiness . Temporary dizziness		. Depression
<b>Gastrointestinal disorders</b>		. Vomiting . Diarrhoea . Constipation	. Nausea	
<b>Hepatobiliary disorders</b>		. Cholestatic jaundice		
<b>Immune system disorders</b>				. Hives
<b>Skin and subcutaneous tissue disorders</b>		. Itching . Acne		. Chloasma

#### 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](http://www.afmps.be); e-mail: [patientinfo@fagg-afmps.be](mailto: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

## 5. HOW TO STORE **UTROGESTAN VAGINAL 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 no longer use. These measures will help protect the environment.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

### **What **UTROGESTAN VAGINAL** contains**

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

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

UTROGESTAN VAGINAL 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 - glycerin - purified water q.s.p. 1 capsule.

### **What **UTROGESTAN VAGINAL** looks like and contents of the pack:**

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

UTROGESTAN VAGINAL 200 mg soft capsules is supplied in boxes of **15** or **45** soft capsules for vaginal 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 VAGINAL 100 mg soft capsules: BE 178954

UTROGESTAN VAGINAL 200 mg soft capsules: BE 279377

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  
1050 Brussels  
Belgium

Medicinal product subject to medical prescription.

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