

UTROGESTAN VAGINAL CAPSULE®

Progesterone (100mg)

What is in this leaflet

1. What Utrogestan is used for
2. How Utrogestan works
3. Before you use Utrogestan
4. How to use Utrogestan
5. While you are using it
6. Side Effects
7. Storage and Disposal of Utrogestan
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Utrogestan is used for

Fertility and pregnancy

- Luteal phase support during in-vitro fertilization cycles (ART) for infertility.
- Threatened miscarriage or prevention of habitual miscarriage.

How does Utrogestan work

Utrogestan contains natural female hormone progesterone. It is identical to the hormone naturally produced in your body, essential to maintain pregnancy.

Utrogestan is for women who needs extra progesterone during fertility treatment (e.g. ART).

If you are having fertility treatment and your doctor has determined that your body does not produce enough progesterone, your doctor may prescribe Utrogestan. The progesterone will help prepare your uterus (womb) to receive and maintain a fertilized egg.

Before you use Utrogestan

- When you must not use it

Do not use Utrogestan if you are allergic to progesterone or any of the inactive ingredients of this medicine, listed at the end of the leaflet. Signs and symptoms of allergic includes:

- Itchy skin, red rashes
- Swollen lips, tongue, eyes or face
- Feeling tight at your chest, trouble of breathing.

Do not take Utrogestan if you have or have had any of the following conditions:

- if you are allergic to soya
- unusual vaginal bleeding that has not been evaluated by your doctor
- known missed abortions or ectopic pregnancy

- severe liver problems
 - known or suspected cancer of the breast or genital tract
 - blood clots (thrombophlebitis or thromboembolic disorder), such as inflammation of a vein, deep vein blood clotting (thrombosis) or a blood clot that travelled to the lungs (pulmonary embolism)
 - bleeding on the brain
 - porphyria disorder (a blood disease)
- If any of the above conditions appear for the first time while taking Utrogestan, stop taking it at once and consult your doctor immediately

Before you start to use it

Talk to your doctor or pharmacist before using Utrogestan.

- Taking other medicines

Please inform your doctor or pharmacist if you are taking or have recently taken or might take any other medicine. This includes medicines obtained without a prescription (from pharmacy, supermarket, convenient shop etc) and any herbal medicines.

How to use Utrogestan

Insert the capsule deep into the vagina using your finger. You may find it easier if you are lying down or squatting.

- How much to use, when to use it, how long to use it

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

For luteal phase support during in vitro fertilization cycles, insert 2 capsules into the vagina in the morning, lunch time and at bedtime; as per instructed by your doctor. Started from the evening of the transfer For luteal phase support during natural cycle, insert 1 capsule into vagina in the morning, and 1-2 capsules in the evening, as instructed by your doctor. Started from the 17th day to 26th day of the cycle for 10 days.

For threatened miscarriage or prevention of habitual miscarriage, insert 4 capsules into the vagina in the morning, and 4 capsules in the evening, as instructed by your doctor.

Insert the capsules one by one when more than one capsule is required. Utrogestan should be used at the same time each day.

Progesterone must be used regularly for it to be effective. Use it according to your doctor's advice. Do not stop using it unless instructed by the doctor.

- If you forget to use it

If you forget to use it, use as soon as you remember it. However, if it is time for the next dose (in less than 12 hours), skip the missed dose. Do not insert a double dose to make up for the dose you missed.

- If you use too much (overdose)

If you use more Utrogestan than you should, stop using it and talk to your doctor or go to hospital. Take the medicine pack with you.

While you are using it

- Things you must do

Talk to your doctor or pharmacist before taking Utrogestan.

- Things you must not do

Utrogestan is not suitable to be used as contraceptive pill. Do not give Utrogestan away to others.

- Things to be careful of

Driving and using machines

Make sure you know how you react to Utrogestan before you drive a car, operate machinery or do anything else that could be dangerous.

Talk to your doctor before taking this medicine if you are breast-feeding. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Side effects

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

With the vaginal insertion, slight irritation of the vaginal area may occur.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the

UTROGESTAN VAGINAL CAPSULE[®]

Progesterone (100mg)

National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Date of Revision:

5/5/2024

Serial No.:

NPRA (R1/2) 29012024/025

Storage and Disposal of Utrogestan**- Storage**

- Store below 30°C.
- Keep in cool dry place. Protect from light.
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after expiry date printed on the box.
- Do not use this medicine if you noticed any visible signs of deterioration of the medicine.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use.

Product Description**- How it looks like**

Utrogestan is round and a slightly yellow soft capsules, containing whitish oily suspension. These are packed in blisters inside a box.

Blister: Aluminium foil/ PVC blister pack with an outer carton; 30 capsules.

- Ingredients

Active Ingredient:

Micronized progesterone.

Inactive ingredients:

Sunflower oil, soybean lecithin, gelatin, glycerol and titanium dioxide.

- MAL Number

MAL19971796ACRZ

Manufacturers

Cyndea Pharma S.L.
Poligono Industrial Emiliano Revilla
Sanz, Avenida de Agreda, 31-42110
Olvega, (Soria), Spain

Product Registration Holder

EP Plus Group Sdn. Bhd.
Block C-3-1, Plaza Mont Kiara,
No. 2, Jalan Kiara, Mont Kiara,
50480 Kuala Lumpur, Malaysia.

UTROGESTAN VAGINAL CAPSULE[®]

Progesterone (100mg)

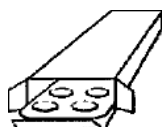
Utrogestan Vaginal administration

Method

1. Wash your hands and vagina before insertion.



2. Remove the soft capsules from the packaging.



3. Choose the position that is most comfortable for you:

(a) Lie on your back with your knees bent, and legs slightly apart

a



(b) Squatting

b



(c) Standing with one leg up

c



4. Gently insert the soft capsule into the vagina.



5. Slowly insert the capsule as deep as possible into your vagina, with the help of your fingers.



Note: insert the capsules one by one when more than one capsules are required. Sanitary pad can be used to protect your underwear from oily ingredient.