

PACKAGE LEAFLET: INFORMATION FOR THE USER

UTROGESTAN VAGINAL® 200mg Capsules

Progesterone

Read all of this leaflet carefully before you start using 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 is and what it is used for
2. What you need to know before you use Utrogestan Vaginal
3. How to use Utrogestan Vaginal
4. Possible side effects
5. How to store Utrogestan Vaginal
6. Contents of the pack and other information

1. What Utrogestan Vaginal is and what it is used for

The name of your medicine is Utrogestan Vaginal 200mg Capsules (called Utrogestan Vaginal in this leaflet).

Utrogestan Vaginal contains a hormone called progesterone.

What Utrogestan Vaginal is used for

Utrogestan Vaginal can be used to help pregnancy.

To help pregnancy

Utrogestan Vaginal is used to assist fertility treatment techniques using your own eggs, such as IVF, gamete intra-Fallopian transfer (GIFT) or zygote intra-Fallopian transfer (ZIFT).

2. What you need to know before you use Utrogestan Vaginal

Do not use Utrogestan Vaginal:

- If you are allergic (hypersensitive) to soya
- If you are allergic to progesterone or any of the other ingredients of this medicine (listed in Section 6)
- If you have severe liver disease
- If you have unexplained vaginal bleeding
- If you have mammary or genital tract carcinoma
- If you have thrombophlebitis
- If you have or have had blood clots in a vein (thrombosis), such as in the legs (deep venous thrombosis) or the lungs (pulmonary embolism)
- If you have cerebral haemorrhage

- If you have a rare blood problem called "porphyria" which is passed down in families (inherited)

Warning and precautions

Utrogestan Vaginal should be used during the first 3 months of pregnancy.

Talk to your doctor or pharmacist before using Utrogestan Vaginal.

Utrogestan Vaginal is not a contraceptive.

If you think you may have miscarried, you should speak for your doctor as you will need to stop using Utrogestan Vaginal.

Children

Utrogestan vaginal is not for use in children.

Other medicines and Utrogestan Vaginal

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Utrogestan Vaginal can affect the way some other medicines work. Also some other medicines can affect the way Utrogestan Vaginal works.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- Bromocriptine used for problems with the pituitary gland or Parkinson's Disease.
- Cyclosporin (used to suppress the immune system).
- Rifamycin medicines such as rifampicin.
- Ketoconazole (used for fungal infections).

Utrogestan Vaginal with food and drink

Utrogestan Vaginal is to be administered intravaginally. Food and drink have no effect on the treatment.

Pregnancy breast-feeding and fertility

- Utrogestan Vaginal will help you become pregnant. See Section 3 on how to use Utrogestan Vaginal.
- Do not use Utrogestan Vaginal if you are breast-feeding.

Driving and using machines

Utrogestan Vaginal has negligible effects on driving or using machinery.

Utrogestan Vaginal contains soya lecithin

Do not use Utrogestan Vaginal if you are allergic (hypersensitive) to soya.

3. How to use Utrogestan Vaginal

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

Please contact the pharmacy if you require an applicator. The applicator supplied by your pharmacy contains a leaflet. This leaflet includes pictures and describes how to use the applicator.

Using this medicine to help pregnancy

- Use this medicine by inserting it deep into the vagina.
- Do not take it by mouth. However, if you take Utrogestan Vaginal by mouth accidentally it will not harm you, only reduce your chances of becoming pregnant.

How much to use

- Your treatment will start the day of embryo transfer.
- Every day, use 200mg of Utrogestan Vaginal in the morning, at lunchtime and at bedtime, or 200mg in the morning and the evening, as instructed by your doctor.
- If there is laboratory evidence of pregnancy, continue with the same dose regime until the 7th to 12th week of pregnancy, as instructed by your doctor.

If you use more Utrogestan Vaginal than you should

If you use more Utrogestan Vaginal than you should, talk to your doctor or go to a hospital. Take the medicine pack with you.

The following effects may happen: feeling dizzy or feeling tired.

If you forget to use Utrogestan Vaginal

- If you forget a dose, insert it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.
- Do not use a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

- Local itching, burning, or discharge.

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 website www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Utrogestan Vaginal

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date stated on the packaging after Exp. The expiry date refers to the last day of that month.
- Store in the original blister pack and in the original outer carton.
- 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 to protect the environment.

6. Contents of the pack and other information

What Utrogestan Vaginal contains

- The active substance is progesterone. Each capsule contains 200mg progesterone.
- The other ingredients are sunflower oil and soybean lecithin. The other ingredients in the capsule shell are gelatin, glycerol, titanium dioxide and purified water.

What Utrogestan Vaginal looks like and contents of the pack

- Utrogestan Vaginal 200mg Capsules are soft and white.
- They are supplied in cartons containing blister strips of 15, 21 or 90 capsules.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for Utrogestan Vaginal is held by Besins Healthcare, Avenue Louise 287, 1050 Brussels, Belgium.

Utrogestan Vaginal is manufactured by:

- Besins Manufacturing Belgium, Groot Bijgaardenstraat 128 1620 Drogenbos, Belgium.
- Cyndea Pharma, S.L. Polígono Industrial Emiliano Revilla Sanz, Avenida de Ágreda, 31, Ólvega 42110 (Soria), Spain.

This medicine is distributed in the UK by: Besins Healthcare (UK) Ltd, 1st Floor, 28 Poland Street, London, W1F 8QN, United Kingdom. Tel: +44(0)203862 0920.

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For information in large print, tape, CD or Braille, telephone +44(0)203862 0920.