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 support pregnancy during in vitro fertilization (IVF) cycles, or to prevent a preterm singleton birth in certain women.

To support pregnancy
Utrogestan Vaginal is for women who need extra progesterone while undergoing treatment in an Assisted Reproductive Technology (ART) program.

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)
• If you are pregnant but your baby has died inside of you (missed abortion)

**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.
• Ciclosporin (used to suppress the immune system).
• Rifamycin medicines such as rifampicin (used to treat infections).
• 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 support pregnancy if you are having fertility treatment. 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 soybean lecithin**
If you are allergic to peanut or soya, do not use this medicinal product.

**3. How to use Utrogestan vaginal**
Always use this medicine exactly as your doctor has told you. 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.

• 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

For support during in vitro fertilization (IVF) cycles:

• Your treatment will start the day of embryo transfer.
• Every day, use 200mg of Utrogestan Vaginal in the morning, at lunchtime and at bedtime, 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.

For prevention of preterm birth in certain women:

• Every day use 200 mg of Utrogestan Vaginal in the evening at bedtime from around week 20 to 34 of pregnancy.

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:

Not known (frequency cannot be estimated from the available data):
• vaginal discharge
• vaginal haemorrhage
• itching

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. 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.
• This medicine does not require any special storage conditions.
• 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 (E171) and water, purified.

What Utrogestan Vaginal looks like and contents of the pack

- Utrogestan Vaginal 200mg Capsules are oval and slightly yellow soft capsules, containing whitish oily suspension.
- They are supplied in cartons containing PVC/Aluminium blisters of 15, 21, 45 or 90 capsules

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for Utrogestan Vaginal is held by Besins Healthcare,
Rue Washington 80
1050 Ixelles
Belgium

Utrogestan Vaginal is manufactured by:
Cyndea Pharma, S.L.
Poligono Industrial Emiliano Revilla Sanz,
Avenida de Agreda, 31,
Ólvega 42110 (Soria),
Spain.

This medicine is distributed in the UK by:
Besins Healthcare (UK) Ltd, Lion Court, 25 Procter Street
London, Holborn, United Kingdom

Tel: +44(0)203862 0920

This medicinal product is authorised in the Member States of the EEA under the following names:
Bulgaria: Utrogestan 200mg vaginal capsules, soft
Croatia: Utrogestan 200 mg meke kapsule za rodnicu.
Czech Republic:progesterone Besins 200 mg mékké tobolky
Estonia: Utrogestan 200 mg vaginaalphmekapslid
Hungary: Utrogestan 200 mg lágy hüvelykapszula
Ireland: Utrogestan Vaginal 200mg Vaginal Capsules, soft
Latvia: Progesterone Besins 200 mg vaginālās mīkstās kapsulas
Lithuania: Progesterone Besins 200 mg minkštosios kapsulės
Netherlands: Utrogestan 200 mg, zachte capsules voor vaginaal gebruik
Norway: Utrogestan 200 mg vaginalkapsler, myke
Poland: Utrogestan 200 mg, kapsułki dopochwowe, miękkie
Slovakia: Utrogestan 200 mg mäkké vaginálné kapsuly
Slovenia: Utrogestan 200 mg mehke vaginalne capsule
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For information in large print, tape, CD or Braille, telephone +44(0)203862 0920.