

Package leaflet: Information for the user

Utrogestan 400 mg soft vaginal 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What <invented name> is and what it is used for
2. What you need to know before you use <invented name>
3. How to use <invented name>
4. Possible side effects
5. How to store <invented name>
6. Contents of the pack and other information

1. What <invented name> is and what it is used for

The name of your medicine is <invented name> (called <invented name> in this package leaflet). <invented name> contains a hormone called progesterone.

What <invented name> is used for

<invented name> can be used to help pregnancy.

To help pregnancy

<invented name> can be used to help women reduce the risk of miscarriage in women with bleeding in the current pregnancy and a history of recurrent miscarriages.

2. What you need to know before you use <invented name>

Do not use <invented name>

- if you are allergic to progesterone, soya, peanut or any of the other ingredients of this medicine (listed in section 6)
- if you have liver problems
- if you have yellowing of the skin or eyes (jaundice)
- if you have undiagnosed vaginal bleeding
- if you have breast cancer or cancer of the genitals

- if you have or have had blood clots in a vein (thrombosis), which can sometimes be painful (thrombophlebitis), for example in the leg (deep vein thrombosis) or the lungs (pulmonary embolism)
- if you have had a cerebral haemorrhage or stroke
- if you have a rare blood disease called porphyria, which is passed down in families (inherited).

Warnings and precautions

<invented name> should only be used during the first 3 months of pregnancy. Talk to your doctor or pharmacist or nurse or mid-wife before using <invented name>.

<invented name> is not a contraceptive.

If you believe that you have had a miscarriage, you must speak with your doctor, because you must stop using Utrogestan.

You must contact your doctor if you:

- experience any vaginal bleeding
- feel unwell within a few days of taking the medicine.

Children and adolescents

<invented name> is not for use in children.

Other medicines and <invented name>

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

This is because <invented name> can affect the way some other medicines work. Also some other medicines can affect the way <invented name> works.

- In particular tell your doctor or pharmacist if you are taking any of the following medicines: Medicine used to help you relax or sleep (phenobarbital, pentobarbital)
- Medicine to control seizure/epilepsy (e.g. phenytoin or carbamazepine)
- Medicine used to treat tuberculosis in particular rifampicin
- Herbal remedies for low mood or anxiety containing St John's wort
- Medicine used to treat fungal infections (e.g. ketoconazole)
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<invented name> with food and drink

<invented name> should be inserted into the vagina. Food and drinks do not affect the treatment.

Pregnancy and breast-feeding

Do not use <invented name> if you are breast-feeding.

Driving and using machines

<Invented name> is not expected to affect your ability to drive or use machines. However, in some people it may cause dizziness and tiredness. If these effects occur, caution is advised in drivers and users of machines .

<invented name> contains soybean lecithin

If you are allergic to peanut or soya, do not use this medicinal product.

<invented name> contains highly refined sunflower oil, which very rarely causes a reaction in adults allergic to refined oils.

3. How to use <invented name>

Always use this medicine exactly as instructed by your doctor. If you have adverse reactions, check with your doctor, pharmacist or nurse or mid-wife.

For treatment to reduce the risk of miscarriage in women with bleeding in the current pregnancy <invented name> should be initiated at the first sign of vaginal bleeding during the first trimester and should continue at least until the 16th week of pregnancy.

Using this medicine to reduce the risk of threatened or recurrent miscarriage

- Insert this medicine deep into the vagina.
- Do not swallow.

How much <invented name> to use

- Use one <invented name> capsule twice daily, one in the morning and one at bedtime, or as instructed by your doctor.
- Continue with the same dose regimen until your doctor tells you to stop.

If you use more <invented name> than you should

If you have use too much <invented name> you should talk to your doctor or got to a hospital. Take the medicine pack with you.

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

If you forget to use <invented name>

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

If you stop using <invented name>

Talk to your doctor, pharmacist or nurse or mid-wife before stopping this medicine.

If you have questions regarding the use of this medicine, talk to your doctor or pharmacist or nurse or mid-wife.

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:

The following side effects may happen with this medicine:

Frequency not known (frequency cannot be estimated from the available data):

- itching
- oily discharge from the vagina
- vaginal haemorrhage
- burning sensation
- dizziness
- feeling very tired (fatigue)

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You may experience short-term tiredness or dizziness within 1 – 3 hours of using the medicine.

If you notice side effects other than those mentioned above, tell your doctor or pharmacist, nurse or mid-wife.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse or mid-wife. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V.* By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <invented name>

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and bottle label after 'EXP'. The expiry date refers to the last day of that month.
- Store in the original packaging.
- 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.
- Do not use this medicine if you notice any changes in the appearance of the capsules

6. Contents of the pack and other information

What <invented name> contains

- The active substance is progesterone. Each soft vaginal capsule contains 400mg of progesterone.
- The other ingredients in the capsule are sunflower oil, soybean lecithin (E322), gelatin (E441), glycerol (E422), titanium dioxide (E171) and purified water.

What <invented name> looks like and contents of the pack

The capsules are oblong, yellowish, (approximately 2.5 cm x 0.9 cm) soft vaginal capsules, containing a whitish oily suspension.

Pack size:

- <Product name> is available in a white high density polyethylene plastic bottle containing 15 soft vaginal capsules.
- PVC/Aluminium blisters of 15, 30 or 45 capsules in a cardboard carton.

Not all pack sizes may be marketed

Marketing Authorisation Holder for <invented name> is held by

<To be completed nationally>

Manufacturer

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

Or

BESINS MANUFACTURING ESPAÑA S.L.
Polígono Industrial El Pitarco, Parcela 4
Muel, 50450 Zaragoza, Spain

This medicine is authorised in the Member States of the European Economic Area under the following names:

Bulgaria, Estonia, Hungary, Croatia, Cyprus, France, Ireland, Italy, Malta, The Netherlands, Norway, Poland, Sweden, Slovenia, Slovakia, Spain: Utrogestan

Belgium, Luxembourg, Portugal: Utrogestan Vaginal

Finland: Lugesteron

Latvia, Lithuania: Progesterone Besins

Czech Republic: Progesteron Besins

Denmark, Iceland: Progestan

This leaflet was last revised in

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