

Orgametril®

5 mg Tablets

Lynestrenol

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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2. Before you take Orgametril
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1. What Orgametril is and what it is used for

Orgametril contains lynestrenol, a progestagen similar to the natural hormone progesterone.

Progestagens, as in Orgametril, are often prescribed for disturbances of the menstrual cycle. Orgametril can also be prescribed:

- for premenstrual syndrome (the regular occurrence of one or more complaints in the period before the menstruation);
- for endometriosis (abnormal growth of the lining of the uterus);
- for treatment of endometrial cancer;
- for the treatment of certain disorders of the breast;
- to suppress the release of an egg cell (ovulation) or menstruation;
- as an adjunct to estrogen therapy during or after the menopause.

2. Before you take Orgametril

Do not take Orgametril if you

- are pregnant or think you may be pregnant;
- have a severe liver disease such as jaundice, inflammation of the liver (hepatitis), tumors of the liver, the rare liver diseases Rotor syndrome or Dubin-Johnson syndrome, or when the liver has not completely recovered from such a severe condition;
- have abnormal vaginal bleeding, which has not been evaluated by your doctor;
- have conditions that deteriorated during pregnancy or during previous use of hormones like: jaundice, severe itching, skin rash (herpes gestationes), a metabolic disease of the liver (porphyria), or a heritable form of hearing loss (otosclerosis);
- are hypersensitive to Orgametril or one of its ingredients.

Take special care with Orgametril

Regular examination by your doctor can be necessary in some cases.

Therefore it is important to tell your doctor if you have or have had any of the following conditions:

- blood clotting disorder (e.g. thrombosis)
- heart or blood vessel disease
- severely depressed mood
- liver disease, such as jaundice, or a tumor in the liver
- abnormal vaginal bleeding
- high cholesterol or other lipids in the blood
- chloasma (brown, blotchy spots on the skin often appearing during pregnancy)
- acne, seborrheic skin and increased body or facial hair

Using other medicines

Other medicines may influence the effects of Orgametril, or

Orgametril may affect other medicines. Ask your doctor or pharmacist for advice before taking any medicine. Tell your doctor if you are using, or are about to use, one of the following medicines:

- rifamycins or troleandomycin (medicines for bacterial infections)
- hydantoins, barbiturates and carbamazepine (medicines for epilepsy)
- aminoglutethimide (medicine for treatment of Cushing syndrome)
- cyclosporine (medicine used after transplantation)
- theophyllines (medicine for asthma, bronchitis and emphysema)
- beta-adrenergic blockers (medicines for high blood pressure or heart conditions)
- insulin (medicine for diabetes)

Pregnancy and breast-feeding

If you are pregnant or you think you may be pregnant, do not take Orgametril.

If you are breastfeeding, do not take Orgametril without asking your doctor first.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Orgametril may cause dizziness. If affected do not drive or use machines.

Important information about some of the ingredients of Orgametril

Orgametril tablets contain lactose. If you have been told by your doctor that you are intolerant to some sugars, contact your doctor before taking this medicinal product.

3. How you take Orgametril

Always take Orgametril exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

For disturbances of the menstrual cycle and some other disorders the usual dosage is: 1 tablet daily on days 14–25 of the cycle. The first day of the cycle is the first day of the menstruation. For the treatment of excessive or prolonged menstrual bleeding the usual dosage is 2 tablets daily for 10 days.

For some other disorders Orgametril has to be taken each day for prolonged periods of time. In that case there is no monthly tablet-free period.

Take the tablets at about the same time each day with a sufficient amount of fluid (e.g. with a glass of water). If you have the impression that the effect of Orgametril is too strong or too weak, talk to your doctor or pharmacist.

If you take more Orgametril than you should:

If you have taken more Orgametril than you should, talk to your doctor or pharmacist immediately. Taking too much Orgametril may cause nausea and vomiting.

If you forgot to take Orgametril:

Take the missed tablet as soon as you remember, unless you are more than 24 hours late. In that case, skip the missed dose. Never take a double dose to make up for a forgotten dose.

Effects when treatment with Orgametril is stopped:

Lynestrenol has a strong influence on the inner lining of the uterus and therefore can be used for the treatment of disturbances of the menstrual cycle. In many cases the cycle can be normalized by taking Orgametril for a number of days per month. A few days (often within three days) after completing the Orgametril course, the inner lining of the uterus will be shed.

This is accompanied by a vaginal bleeding (like a normal menstruation).

4. Possible side effects

Orgametril may cause side effects, depending on the dosage and sensitivity of the patient. The following side effects have been reported:

Hypersensitivity, fluid accumulation in the tissues (fluid retention), slightly increased blood sugar after a meal (reduced glucose tolerance), changes in lipid and cholesterol levels in the blood, nervousness, depressed mood, increase or decrease of sexual desire (libido), headache, migraine, dizziness, nausea, vomiting, abdominal pain, diarrhea, constipation, jaundice (icterus), increased sweating, chloasma (pregnancy spots, i.e. patchy discoloration of the skin), itching, oily skin (seborrhea), acne, skin reactions, increased body or facial hair, vaginal bleeding (in between the normal periods) mainly during the first two months, sensitive breasts, absence of menstruation, change in vaginal secretion.

If you notice any of these side effects contact your doctor, especially when you experience vaginal bleeding that has not been evaluated by your doctor.

If you notice a side effect not mentioned in this leaflet or you experience a serious side effect, inform your doctor or pharmacist.

5. Storing Orgametril

Keep Orgametril out of reach and sight of children.

Store at 2–30 °C. Store in original package to protect from light and moisture.

Do not use Orgametril after the date stated on the package following 'do not use after' or 'exp'.

6. Further information

What Orgametril contains

The active substance of Orgametril is lynestrenol. The other ingredients are potato starch, alpha-tocopherol, glycerol, magnesium stearate, talc and lactose monohydrate.

What Orgametril looks like and contents of the pack

White, round scored tablets marked 'Organon' on one side; the other side is marked with the code 'TT' above and the code '4' below the score line. 1 push-through strip with 30 scored tablets of 5 mg.

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This leaflet was revised on July 2007

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers &
Union of Arab Pharmacists