

ORGAMETRIL
(LYNESTRENOL)
(For oral use only)

Composition

Each tablet contains:
5 mg lynestrenol (ph.Eur.Spec.)

Characteristics

Pharmacodynamics

Orgametril is an oral preparation of the synthetic progestagen, which shares various activities with the natural hormone progesterone. Lynestrenol has a strong progestational influence on the endometrium. In addition it suppresses the ovulation and menstruation for as long as the preparation is taken daily without interruption. Orgametril can be used in conditions requiring a pronounced progestagenic effect.

Pharmacokinetics

After oral administration lynestrenol is readily absorbed and subsequently converted in the liver into the pharmacologically active norethisterone. Within 2-4 hours after ingestion of lynestrenol peak plasma levels of norethisterone is reached. Lynestrenol and its metabolites are predominantly excreted in the urine, and to a lesser extent in the feces.

N.B: Through out the text, take the first day of bleeding as first day of the cycle.

Indications

- Polymenorrhea
- Menorrhagia and metrorrhagia
- Selected cases of primary and secondary amenorrhea and oligomenorrhea
- Endometriosis
- Selected cases of endometrial carcinoma
- Benign breast disease
- Suppression of ovulation, ovulation pain and menstruation; dysmenorrhea
- Postponement of menstruation
- As an adjunct to estrogen therapy in peri- and postmenopause, in order to avoid endometrial hyperplasia

Polymenorrhea:

1 tablet daily on days 14-25 of the cycle.

Menorrhagia and metrorrhagia:

2 tablets daily for 10 days. Usually the bleeding will cease within a few days after the start of the treatment. Treatment is repeated during the next 3 menstrual cycles with 1 tablet daily on days 14-25 of each cycle. Further diagnostic procedures are necessary if the complaints do not disappear during or after this treatment.

Selected cases of primary and secondary amenorrhea and oligomenorrhea:

Treatment should start with the administration of an estrogen, e.g. 0.02 -0.05 mg ethinylestradiol per day for 25 days. In conjunction with this, 1 tablet daily of Orgametril is administered on days 14-25. After cessation of treatment, a withdrawal bleeding usually occurs within 3 days. Treatment is resumed (second cycle) starting on day 5 of this withdrawal bleeding with the estrogen given on days 5-25 of the cycle and again with one tablet daily of Orgametril on days 14-25. This treatment should be repeated for at least another cycle.

Premenstrual syndrome.

1 tablet daily on days 14 – 25 of the cycle.

Endometriosis:

1-2 tablets daily for at least 6 months.

Selected cases of endometrial carcinoma:

6-10 tablets daily for prolonged periods.

Benign breast disease:

1 tablet daily on days 14-25 of the cycle for at least 3-4 months.

Suppression of menstruation, ovulation and ovulation pain; dysmenorrhea:

Treatment with 1 tablet daily should start preferably on day 1, but no later than day 5 of the cycle. The treatment can be continued for many months (without tablet-free days). If in spite of treatment, breakthrough bleeding occurs, the dosage should be increased to 2 or 3 tablets daily for 3-5 days.

Post-ponement of menstruation:

Treatment with 1 tablet daily should start preferably 2 weeks before the expected onset of menstruation. If treatment is started less than 1 week before the expected onset of menstruation the dosage should be 2-3 tablets per day. However, in that case a delay of more than 1 week is undesirable. The risk of breakthrough bleeding increases if treatment is started later.

Therefore, treatment should not be started later than 3 days before the expected onset of menstruation.

As an adjunct to estrogen therapy in pre- and post menopause, in order to avoid endometrial hyperplasia:

½ - 1 tablet daily for 12-15 days per month, e.g. on the first 2 weeks of every calendar month; the estrogen can be administered daily without tablet-free intervals at the lowest effective dose.

Administration

Orgametril tablets should be taken orally with some fluid.

Contraindications

- Pregnancy or suspected pregnancy.
- Severe liver disease such as cholestatic jaundice or hepatitis (or a history of severe liver disease if the results of liver function tests have failed to return to normal), hepatic cell tumors, Rotor syndrome and Dubin-Johnson syndrome.
- Undiagnosed vaginal bleeding.
- Conditions of rare occurrence known to be affected by sex steroids, or a history of these conditions (the condition may have occurred first or worsened during pregnancy or during treatment with sex steroids), i.e. Herpes gestationis, jaundice of pregnancy, otosclerosis, severe pruritis, or porphyria.

Use during Pregnancy and Breast feeding

This medicine is contraindicated during pregnancy. There are insufficient data on the use of this medicine during breast-feeding to assess potential harm.

Warnings and Special Precautions

- Chloasma is occasionally seen during the use of estrogen and/or progestagen-containing preparations, especially in women with a history of chloasma gravidarum. In women with a tendency to develop chloasma, exposure of the skin to natural or artificial sunlight may induce or aggravate the condition.
- Occasionally changes in parameters of liver function, carbohydrate metabolism and haemostasis may occur. If the results of relevant test become abnormal, treatment should be discontinued. An increase in LDL and a decrease in HDL cholesterol may occur during Orgametril therapy.
- During prolonged treatment with progestagens, periodic medical examinations are advisable.
- As determined by the effects on SHBG, lynsterol has weak androgenic activity. This is confirmed by slight signs of virilization (mainly acne and Hirsutisum) observed in some patients.
- Patients with any of the following conditions should be examined regularly:
 - circulatory disorders (or a history of this condition), since with estrogen/progestagen-containing oral contraceptive preparations a slightly increased risk of specific cardiovascular disorders have been reported;
 - some forms of severe depression if likely to be exacerbated by sex steroids.

Interactions

There are some interactions, mainly obtained with other progestagen containing preparations, activated charcoal, barbiturates (primidone included). Hydantoins and Rafampicin may possibly decrease the effectiveness of Orgametril. Conversely, Orgametril may possibly increase the effectiveness of certain beta-adrenergic blockers and cyclosporin and decrease the effectiveness of insulin.

Adverse Reactions

During continuous treatment regimens with Orgametril, breakthrough bleeding or spotting will occur frequently(over 10%) during the first two months. Later on the frequency gradually decreases.

During cyclic treatment regimens break through bleeding or spotting will be seen occasionally(1-10%).

Temporarily increasing the dose will control the bleeding in most cases.

Other adverse events which occur frequently (over 10 %) are: change in Libido (both increase and decrease), nausea or other gastrointestinal disturbances, and weight increase. Adverse events which may be observed occasionally (1-10%) or rare (less than 1 %) are: Headache or migraine, dizziness, nervousness, depression, sweating, acne, hirsutism, chloasma, rash, pruritus, jaundice, change in lipoprotein profile, alterations in liver function tests , amenorrhoea, menstrual irregularity , reduced glucose tolerance, breast pain, oedema. Most of these adverse events are transient and of minor importance in many cases.

Over dosage

The toxicity of lynestrenol is very low. In case of overdose, e.g. young children taking several tablets simultaneously, no toxic symptoms are expected to occur. Symptoms that may occur are nausea and vomiting. There is no necessity for specific treatment. If necessary, symptomatic treatment can be given.

Presentation

Pack of 1x30's physician.

Instructions

Store at 2-30°C. Protect from sunlight and moisture.

Keep out of the reach of children.

Manufactured by:

N.V. Organon, Oss,
The Netherlands.

For:

OBS Paksitan (Pvt.) Limited.
C-14, S.I.T.E.,
Karachi – 75700 - Pakistan

Mfg. Org. Spec.

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In correspondence please quote packing number.