Orgatril®

Lynestrenol BP 5 mg

Composition

Each tablet contains Lynestrenol BP 5 mg.

Characteristics

Pharmacodynamics. **Orgatril®** is an oral preparation of the synthetic progestagen lynestrenol, which shares various activities with the natural hormone progesterone. Lynestrenol has a strong progestational influence on the endometrium. In addition, it suppresses ovulation and menstruation for as long as the preparation is taken daily without interruption.

Orgatril® can be used in conditions requiring a pronounced progestagenic effect. Pharmacokinetics. After oral administration lynestrenol is readily absorbed and subsequently converted into the pharmacologically active norethisterone, through which it exerts its major biological effects. Within 2-4 hours after ingestion of lynestrenol peak plasma levels of norethisterone are reached. Lynestrenol and its metabolites are predominantly excreted in the urine, and to a less extent in the faeces.

Indications Dosage

N.B. : Throughout the text, take the first day of the menstrual bleeding as day 1 of the cycle.

Polymenorrhoea	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 amenorrhoea and oligomenorrhoea.	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 **Orgatril®** 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 1 tablet daily of **Orgatril®** 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; dysmenorrhoea.	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, a breakthrough bleeding occurs, the dosage should be increased to 2 or 3 tablets daily for 3-5 days.
Postponement 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 postmenopause, in order to avoid endometrial hyperplasia.	$^1/_2$-1 tablet daily for 12-15 days per month, e.g. for the first 2 weeks of every calendar month; the estrogen may be administered daily without tablet-free intervals at the lowest effective dose.

Administration

Orgatril® tablets should be taken orally with some fluid.

Contraindication

- 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 tumours, 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 use of sex steroids); i.e. herpes gestationis, jaundice of pregnancy otosclerosis, severe pruritus 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 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 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 tests become abnormal, treatment should be discontinued. An increase in LDL-cholesterol and a decrease in HDL-cholesterol may occur during **Orgatril®** therapy.
- During prolonged treatment with progestagens, periodic medical examinations are advisable.
- As determined by the effects on SHBG, lynestrenol has weak androgenic activity. This is confirmed by the slight signs of virilisation (such as acne and hirsutism) observed in some patients.
- Patients with any of the following conditions should be kept under close medical supervision:
  - circulatory disorders (or a history of this condition), since with estrogen/progestagen -containing oral contraceptive preparations a slightly increased risk of some cardiovascular disorders has been reported;
  - some forms of severe depression, if likely to be exacerbated by sex steroids.

Interactions

There are some indications, mainly obtained with other progestagen-containing preparations, that activated charcoal, barbiturates (primidone included), hydantoins and rifampicin may possibly decrease the effectiveness of **Orgatril®**. Conversely, **Orgatril®** may possibly increase the effectiveness of certain beta-adrenergic blockers and cyclosporin and possibly decrease the effectiveness of insulins.

Adverse reactions

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

During cyclic treatment regimens breakthrough bleeding and spotting will be seen occasionally (1-10 per cent). Temporarily increasing the dose will control the bleeding in most cases.

Other adverse events which occur frequently (over 10 per cent) 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 per cent) or rare (less than 1 per cent) are : headache or migraine, dizziness, nervousness, depression, increased 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.

Storage Condition

Store in a cool & dry place, away from light. Keep the medicine out of the reach of children.

Commercial Pack

Orgatril® Tablet: Each box contains 3x10 tablets in Alu-PVC blister strip.

Manufactured by:
Nuvista Pharma Limited
Tongi - Gazipur

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