

Norestin®

Norethisterone

Tablet

Description

Norestin® is the preparation of Norethisterone. Norethisterone is a molecule used in some combined oral contraceptive pills, progestogen only pills and is also available as a stand-alone drug. If contraceptive protection is required, additional non hormonal contraceptive methods should be used.

Indication

- Spasmodic Dysmenorrhea
- Management of perimenopausal symptoms
- Premenstrual tension
- Management of endometriosis
- For Dysfunctional Uterine Bleeding
- Prophylaxis against recurrent dysfunctional bleeding
- For the treatment of inoperable cancer of the breast
- For postponement of menstruation
- Menorrhagia

Dosage and Administration

For Spasmodic Dysmenorrhea: 3 (15 mg) Norestin® tablet daily from days 5 to 26 of the cycle, but anovulation and contraception cannot be guaranteed with the same degree of confidence.

For Management of perimenopausal symptoms: 1/2-2 (2.5-10 mg) Norestin® tablet daily from days 5 to 26 of the cycle, in premenopausal women or for 3 weeks out of 4 in postmenopausal women is sometimes effective in relieving climacteric symptoms when the use of estrogen is contraindicated. Postmenopausal osteoporosis can also be prevented with 2 (10 mg) Norestin® tablet daily, and treated with 1 α -hydroxycholecalciferol combined with Norethisterone.

More commonly Norestin® combined with estrogen is used for this purpose. Norestin® given cyclically, is intended to protect the uterus from unopposed exogenous estrogen, which can give rise to endometrial hyperplasia and even endometrial carcinoma.

For Premenstrual Tension: 1-3 (5-15 mg) Norestin® tablet daily from days 19 to 26, for two to three cycles at a time.

As a Prophylaxis against recurrent dysfunctional bleeding: 1 Norestin® tablet 2 times daily from the 16 to the 25 day of the cycle. Withdrawal bleeding occurs a few days after administration of the last tablet.

For Management of endometriosis: Treatment should begin between the 1st and 5th day of the cycle with 1 Norestin® tablet

twice daily. In the event of spotting, the dose can be increased to 2 tablets twice daily. If bleeding ceases, dose reduction to the initial dose should be considered. Treatment continues for at least 4 to 6 months. With uninterrupted daily intake, ovulation and menstruation do not usually occur. After discontinuation of hormone treatment a withdrawal bleeding will occur.

For Dysfunctional Uterine Bleeding: 1 Norestin® tablet 3 times daily for 10 days. Usually bleeding stops within 1-3 days. About 2 to 4 days after completion of the treatment a withdrawal bleeding will occur which is similar to the intensity and duration of normal menstruation. Occasionally, slight bleeding may occur after the initial suspension of bleeding. If this happens tablet taking should not be interrupted or stopped. If vaginal bleeding does not stop, despite correct tablet intake, you should contact with your doctor, as another type of treatment and/or investigation may be necessary. To prevent bleeding recurrence, Norestin® should be taken in each cycle 1 tablet 1 to 2 times daily from the 16th to the 25th day of the cycle. (The first day of the cycle is the first day of monthly bleeding).

For the treatment of inoperable cancer of the breast: Norestin® tablet should be used in inoperable primary or recurrent carcinoma of the breast. The dose for Norestin® tablet should be 6-8 tablets (30-40 mg) daily in divided doses. If no subjective or objective response occurs within 6 weeks, the dose is increased to 60 mg daily and may be continued indefinitely.

For postponement of menstruation: 1 Norestin® tablet three times daily starting from 3 days before the expected onset of menstruation. A normal period should occur 2-3 days after the patient has stopped taking tablets.

For Menorrhagia: Treatment with 1 Norestin® tablet 3 times daily from 5-25 days of the cycle has been shown to be effective in reducing menstrual blood loss.

Norethisterone is not to use in children and elderly people.

Side Effects

- Breakthrough bleeding.
- Spotting.
- Change in menstrual flow.
- Amenorrhoea.
- Edema.
- Changes in weight (decreases, increases).

- Changes in cervical erosion and cervical secretions.
- Cholestatic jaundice.
- Rash (allergic) with and without pruritus.
- Melasma or chloasma.
- Mental depression.
- Acne.
- Breast enlargement/tenderness.
- Headache/migraine.
- Urticaria.
- Abnormalities of liver tests (i.e., AST, ALT, Bilirubin).
- Mood swings.
- Nausea.
- Insomnia.

Use in Pregnancy and Lactation

Norethisterone has been assigned to pregnancy category X by the FDA. Norethisterone is considered contraindicated during pregnancy.

Norethisterone is excreted into human milk in small amount. It should be avoided during lactation.

Precaution

Norethisterone should be used with caution in patients with medical history, including any allergies (especially drug allergies), abnormal vaginal bleeding, liver, kidney or heart disease, cancer of the breast or genitals, missed abortion, blood clots, seizures, migraine, asthma, depression or diabetes. Limit alcohol, as this may increase side effects of this drug. Norethisterone should be used with caution in patients with cardiovascular or renal impairment, diabetes mellitus, asthma, epilepsy, and migraine or other conditions which may be aggravated by fluid retention. They should also be used with care in persons with a history of depression. High doses should be used with caution in patients susceptible to thromboembolism. It should not be given to the patients with undiagnosed vaginal bleeding, nor to those with a history or current high risk of arterial disease and should generally be avoided in hepatic impairment, especially if severe.

Contraindications

Norethisterone should not be used in the presence of the conditions listed below. If any of the conditions appear during the use of Norethisterone, the use of the preparation must be discontinued immediately.

- Known or suspected Pregnancy
- Lactation
- History of herpes gestationalis, cholestatic or idiopathic jaundice
- Dubin-Johnson and Rotor Syndrome
- Undiagnosed abnormal vaginal bleeding
- Hirsutism
- Desire for pregnancy during continuous treatment
- Known or suspected sex hormone dependent malignancies

Drug Interactions

Norethisterone is known to interact with other drugs like Cyclosporin, Estrogens, Griseofulvin, Phenytoin, Rifampicin. These interactions are sometimes beneficial and sometimes may cause threats to life. Always consult your physician for the change of dose regimen or an alternative drug of choice that may strictly be required.

Overdose

Signs of an overdose include feeling or being sick, breast enlargement or vaginal bleeding. In case of overdose contact your doctor immediately.

Storage

Keep in a cool and dry place. Protect from light. Keep out of the reach of children.

Commercial Pack

Norestin® tablet: Box containing 60 tablets in 6X10's blister strips. Each tablet contains Norethisterone BP 5 mg.



Manufactured by:
Nuvista Pharma Limited
 48 Tongi industrial area, Gazipur, Bangladesh
 A subsidiary of Beximco Pharmaceuticals Ltd.

