

# Ethinor®

Norethisterone BP tablet

## DESCRIPTION

**Ethinor®** is a preparation of Norethisterone. Norethisterone is a synthetic, potent, orally active progestogen which, by virtue of its progestogenic effects, produces secretory effects on oestrogen-primed genital tissue, has a sedative effect on uterine muscle and a stypitic effect on uterine haemorrhage. Norethisterone also has some androgenic effects and some weak oestrogenic activity.

## INDICATIONS

At low dose:

- ▶ Dysfunctional Uterine Bleeding (Metropathia haemorrhagica)
- ▶ Pre-menstrual syndrome
- ▶ Postponement of menstruation
- ▶ Dysmenorrhoea
- ▶ Endometriosis
- ▶ Menorrhagia

At high dose:

- ▶ Disseminated carcinoma of the breast.

## DOSAGE AND ADMINISTRATION

Unless otherwise prescribed by the doctor, the following dosages are recommended.

### Low dose

1. Metropathia haemorrhagica (dysfunctional uterine bleeding): 5 mg three times daily for ten days. Bleeding is arrested usually within one to three days. A withdrawal bleeding resembling normal menstruation occurs within two to four days after discontinuing treatment.

Prophylaxis of recurrence of dysfunctional bleeding: if there are no signs of resumption of normal ovarian function (no rise of morning temperature in the second half of the cycle), recurrence must be anticipated. Cyclical bleeding can be established with 5mg twice daily from the 19th to the 26th day of the cycle.

2. Pre-menstrual syndrome (including pre-menstrual mastalgia): Pre-menstrual symptoms such as headache, migraine, breast discomfort, water retention, tachycardia and psychic disturbances may be relieved by the administration of 10 - 15 mg daily from the 19th to the 26th day of the cycle. Treatment should be repeated for several cycles. When treatment is stopped, the patient may remain symptom free for a number of months.

3. Postponement of menstruation: In cases of too frequent menstrual bleeding, and in special circumstances (e.g. operations, travel, sports) 5 mg three times daily, starting three days before the expected onset of menstruation. A normal period should occur two to three days after the patient has stopped taking tablets.

4. Dysmenorrhoea: Functional or primary dysmenorrhoea is almost invariably relieved by the suppression of ovulation. 5mg three times daily for 20 days, starting on the fifth day of the cycle (the first day of menstruation counting as day one). Treatment should be maintained for three to four cycles followed by treatment-free cycles. A further course of therapy may be employed if symptoms return.

5. Endometriosis (pseudo-pregnancy therapy): long-term treatment is commenced on the fifth day of the cycle with 10 mg daily for the first few weeks. In the event of spotting, the dosage is increased to 20mg and, if necessary, 25 mg daily.

After bleeding has ceased, the initial dose is usually sufficient. Duration of treatment: four to six months continuously, or longer if necessary.

6. Menorrhagia (hypermenorrhoea): 5 mg two to three times a day from the 19th to the 26th day of the cycle (counting the first day of menstruation as day one).

### High dose

1. For disseminated breast carcinoma the starting dose is 8 tablets (40 mg) per day increasing to 12 tablets (60 mg) if no regression is noted.

2. Not for use in children.

3. Not for elderly patients

The tablets are to be swallowed whole with some liquid.

## CONTRAINDICATION AND WARNINGS

Known hypersensitivity to Norethisterone.

Pregnancy, hepatic impairment or hepatic disease, history during pregnancy of idiopathic jaundice, severe pruritus, pemphigoid gestationis or herpes gestationis. Undiagnosed vaginal bleeding. History or current high risk of arterial disease. Breast or genital tract carcinoma,

unless norethisterone is being used as part of the management of these conditions. Porphyria. Hepatic tumour or a history of hepatic tumour. Patients with previous idiopathic or current venous thromboembolism (deep vein thrombosis, pulmonary embolism).

### Reasons for immediate discontinuation of the tablets

Occurrence for the first time of migrainous headaches or more frequent occurrence of unusually severe headaches, sudden perceptual disorders (eg disturbances of vision or hearing), first signs of thrombophlebitis or thromboembolic symptoms (for example, unusual pains in or swelling of the legs, stabbing pains on breathing or coughing for no apparent reason), a feeling of pain and tightness in the chest, pending operations (six weeks beforehand), immobilisation (for instance, following accidents), onset of jaundice, onset of anicteric hepatitis, generalised pruritus, significant rise in blood pressure, pregnancy.

### Other

Strict medical supervision is necessary if the patient suffers from diabetes.

## SPECIAL PRECAUTIONS

Diabetes mellitus must be actively excluded as this disease requires careful supervision. The requirements for oral antidiabetics or insulin may change.

Chloasma may occasionally occur, especially in women with a history of chloasma gravidarum. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation when taking Norethisterone.

Patients who have a history of psychic depression should be carefully observed and the drug discontinued if the depression recurs to a serious degree.

Norethisterone also has estrogenic properties due to its partial conversion to the estrogen ethinylestradiol. There were no corresponding estrogen-related safety relevant findings during the long period of post-marketing surveillance.

## SIDE-EFFECTS

Undesirable effects are more common during the first months after start of intake of norethisterone, and subside with duration of treatment.

Side-effects rarely occur with doses of 15 mg daily.

Gastrointestinal disorders: nausea, abdominal pain and vomiting,

Amongst those recorded are slight nausea, exacerbation of epilepsy and migraine. With extremely high dosage there may be cholestatic live changes.

## OVERDOSAGE

There have been no reports of ill-effects from over dosage and treatment is generally unnecessary. There are no special antidotes and treatment should be supportive and symptomatic.

## DRUG INTERACTION

Drug interactions, which result in an increased clearance of sex hormones, can lead to decreased therapeutic efficacy. This has been established with many hepatic enzyme-inducing drugs (including phenytoin, barbiturates, primidone, carbamazepine and rifampicin); griseofulvin, oxcarbazepine, and rifabutin are also suspected.

It should be administered with caution together with enzyme inducers (they may accelerate its metabolism).

## USE IN PREGNANCY AND LACTATION

Norethisterone is contraindicated in pregnancy and should be avoided during lactation, as it is present in breast milk.

Hypospadias in males and virilisation of females has been reported in the offspring of mothers who have taken Norethisterone during pregnancy.

## PHARMACEUTICAL PRECAUTION

Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

## PACKAGING

**Ethinor®** tablet: Box containing 3 strips of 15 tablets each. Each tablet contains Norethisterone BP 5 mg.

## SK-F

Manufactured for

**ESKAYEF PHARMACEUTICALS LTD.**

By POPULAR PHARMACEUTICALS LTD.

GAZIPUR, BANGLADESH

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