

NORMENS®

Micronized Norethisterone acetate BP

Presentation: Each white, uncoated tablet contains Micronized Norethisterone acetate BP equivalent to 5mg norethisterone.

Uses: Dysfunctional Uterine Bleeding (DUB), Premenstrual syndrome, Postponement of menstruation, Endometriosis, Menorrhagia, Dysmenorrhoea, Prevention of lactation, Mastalgia. A total dose of about 100-150mg **NORMENS®** (10-15mg on each of 10 consecutive days) will produce complete secretory transformation of an endometrium that has been subjected to the proliferative effect of oestrogens.

A particular advantage is that menstruation like withdrawal bleeding occurs consistently two to three days after **NORMENS®** is stopped.

Dosage and administration: The use of **NORMENS®** is restricted to patients in whom there is no possibility of early pregnancy in the cycle concerned.

Metropathia haemorrhagica (dysfunctional uterine bleeding): 1 tablet 3 times daily for 10 days. Bleeding is arrested usually within 1-3 days. A withdrawal bleeding resembling normal menstruation occurs within 2-4 days after discontinuing treatment.

Prophylaxis against recurrence of dysfunctional bleeding: If there are no signs of resumption of normal ovarian function (no rise in the second half of the cycle of the morning temperature, which should be measured daily) recurrence must be anticipated. Cyclical bleeding can be established with 1 tablet twice daily from the 19th to the 26th day of the cycle.

Premenstrual syndrome (including premenstrual mastalgia): Premenstrual symptoms such as headache, migraine, breast discomfort, water retention, tachycardia and psychological disturbances may be relieved by the administration of 2-3 tablets 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.

Postponement of menstruation: In case of too frequent menstrual bleeding, and in special circumstances (e.g. travel, sports) the postponement of menstruation is possible. 1 tablet **NORMENS®** three times daily, starting 3 days before the expected onset of menstruation. A normal period should occur 2-3 days after the patient has stopped taking tablets.

Endometriosis : Long term, treatment is commenced on the 5th day of the cycle with 2 tablets **NORMENS®** daily for the first few weeks. In the even of spotting, the dosage is increased to 4, and if necessary 5 tablets daily.

After bleeding has ceased, the initial dose is usually sufficient. Duration of treatment : 4-6 months continuously, or longer if necessary.

Menorrhagia (hypermenorrhoea) : 1 tablet 2-3 times a day from the 19th to the 26th day of the cycle (counting the first day of menstruation as day 1).

Dysmenorrhoea: Functional or primary dysmenorrhoea is almost invariably relieved by the suppression of ovulation. 1 tablet three times daily for twenty days, starting on the 5th day of the cycle (the first day of menstruation counting as day 1). 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.

Note: If menstrual bleeding should fail to follow a course of **NORMENS®**, the possibility of pregnancy must be ruled out before a further course is given.

Contra-indications, warnings, etc.

Contra-indications: Pregnancy, Severe disturbances of liver function, Dubin-Johnson and Rotor syndromes, Previous or existing liver tumours. History during pregnancy of idiopathic jaundice, severe pruritus or herpes gestationis (also known as pemphigoid gestationis). Current thromboembolic processes.

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 (e.g. disturbance of vision or hearing), first signs of thrombophlebitis or thromboembolic symptoms, a feeling of pain and tightness in the chest, pending operations (six weeks beforehand), immobilization (for instance, following accidents), onset of jaundice, hepatitis, general pruritus, significant rise in blood pressure, pregnancy.

Warnings: There is a general opinion, based on statistical evidence that users of combined oral contraceptives experience, more often than non-users, venous thromboembolism, arterial thrombosis, including cerebral and myocardial infarction, and subarachnoid haemorrhage. Full recovery from such disorders does not always occur, and it should be realized that in a few cases they are fatal. Although **NORMENS®** does not contain oestrogen, one should keep the possibility of an increased thromboembolic risk in mind, particularly where there is a history of thromboembolic disease or in the presence of severe diabetes with vascular changes or sickle-cell anemia.

NORMENS® can influence carbohydrate metabolism. Parameters of carbohydrate metabolism should be examined carefully in all diabetics before and regularly during treatment.

In rare cases benign and in even rarer cases malignant liver tumors, leading in isolated cases to life-threatening intra-abdominal hemorrhage, have been observed after the use of hormonal substances such as the one contained in **NORMENS®**. If severe upper abdominal complaints, liver enlargement or signs of intra-abdominal haemorrhage occur, a liver tumor should be considered in the differential diagnosis and, if necessary, the preparation should be withdrawn.

Side-effects: Rarely occur in doses of 15 mg daily. Amongst those recorded are slight nausea, exacerbation of epilepsy and migraine. With extremely high dosage there may be cholestatic liver 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 symptomatic.

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

Pharmaceutical precautions: Store in cool dry conditions (below 30°C). Keep the medicine away from children.

Package quantities: Each box contains 10x10's tablets in blister strips.

® Trade Mark

Manufactured By
 **Renata Limited**
Rajendrapur, Gazipur, Bangladesh.
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