Only for the use of Medical Professionals

Menogia®

Norethisterone

Composition

Menogia® tablet: Each tablet contains Norethisterone BP 5 mg.

Pharmacology

Menogia® is the preparation of Norethisterone which is a potent, orally active synthetic progestogen. Norethisterone has the typical effects of a progestogen and converts the endometrium from the proliferative to the secretory phase. In the body, Norethisterone works much like natural progesterone produced by the ovaries and the placenta and is used to treat a number of disorders of the menstrual cycle.

Indication

Menogia® is indicated for the treatment of-

- Dysfunctional uterine bleeding
- Menorrhagia
- Primary and secondary amenorrhea
- Endometriosis
- Dysmenorrhea
- Premenstrual syndrome (PMS)
- Postponement of menstruation
- Disseminated carcinoma of the breast

Dose and administration

Route of administration: **Menogia®** should be taken in oral route.

Dysfunctional uterine bleeding (DUB): One **Menogia®** tablet (5 mg) 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, patient should contact with the doctor, as another type of treatment and/or investigation may be necessary. To prevent bleeding recurrence, **Menogia®** should be taken in each cycle 1 tablet 1 to 2 times daily from the 16^{th} to the 25^{th} day of the cycle. (The first day of the cycle is the first day of monthly bleeding).

Menorrhagia: One **Menogia®** tablet (5 mg) 3 times daily from day 5 to 25 of the cycle has been shown to be effective in reducing menstrual blood loss.

Primary and secondary amenorrhea: Hormone treatment of secondary amenorrhea can be carried out only after the exclusion of pregnancy. Before treatment of primary or secondary amenorrhea is commenced the presence of a prolactin-producing pituitary tumour should be excluded. The possibility cannot be ruled out that macroadenomas increase in size when exposed to high doses of oestrogen for prolonged periods of time. Endometrial priming with an oestrogen must be carried out (e.g., for 14 days) before beginning treatment with **Menogia®**. Thereafter 1 tablet of **Menogia®** is given 1 to 2 times daily for 10 days. Withdrawal bleeding occurs within a few days after intake of the last tablet. In patients in whom sufficient endogenous oestrogen production has been achieved, an

attempt can be made to stop the oestrogen treatment and to induce cyclical bleeding by administering 1 tablet of **Menogia®** twice daily from the 16th to the 25th day of the cycle.

Endometriosis: Treatment should begin between the 1st and 5th day of the cycle with 1 **Menogia®** 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.

Dysmenorrhea: One **Menogia®** tablet (5 mg) thrice daily from day 5 to day 26 of the cycle, but anovulation and contraception cannot be guaranteed with the same degree of confidence.

Premenstrual syndrome: One **Menogia®** tablet (5 mg) 2 to 3 times daily from days 19 to 26 for 2 to 3 cycles at a time.

Postponement of menstruation: One **Menogia®** tablet (5 mg) 3 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.

Disseminated carcinoma of breast: Eight **Menogia®** tablet (40 mg) daily, increased to 60 mg (12 tablets) daily if no regression is noted.

Contraindication

Norethisterone is contraindicated in patients with known hypersensitivity to norethisterone or any components of this product. It is also contraindicated in patients with a history of venous or arterial thrombotic or thromboembolic events (e.g., deep venous thrombosis, pulmonary embolism, myocardial infarction), presence or a history of prodromi of a thrombosis (e.g., transient ischemic attack, angina pectoris), history of migraine with focal neurological symptoms, diabetes mellitus with vascular involvement, presence or history of severe hepatic disease as long as liver function values have not returned to normal, presence or history of liver tumors (benign or malignant) and known or suspected sex hormone dependent malignancies.

Warning and precaution

Precautions should be exercised in case of patients with hypertension, CVS disease, hepatic impairment, epilepsy, new onset of migraine type headache, asthma, renal impairment, history of clinical depression and other conditions that may cause fluid retention.

Side effects

The most common side effects of norethisterone are uterine or vaginal bleeding including spotting, hypomenorrhea, amenorrhea, headache, nausea and edema. Some uncommon side effects include migraine, hypersensitivity reactions, urticaria, rash, visual disturbance and dyspnea.

Use in pregnancy and lactation

Pregnancy: Norethisterone is pregnancy category D. It is contraindicated in pregnancy.
Lactation: Norethisterone should not be used during lactation.

Use in children and adolescent

Norethisterone is only indicated after menarche.

Drug interaction

Drug interaction with medication: Antidepressants, antituberculous drugs, antiepileptics (e.g., carbamazepine, oxcarbazepine, phenytoin, topiramate, and barbiturates), antifungals and antiviral

drugs enhance the metabolism of norethisterone. Norethisterone may antagonize the effect of anti-diabetics. So readjustment of dose of anti-diabetics may be required.

Drug interaction with foods: Not applicable

Drug interaction with others: Effects of norethisterone will be altered if other sex hormones are prescribed simultaneously. CYP450 hepatic enzymes may be affected by drug interaction resulting in either induction or inhibition of drug metabolism.

Overdose
There are no reports of ill effects found for overdosage and treatment is generally unnecessary. There is no specific antidote and treatment should be symptomatic.

Storage
Store in a cool and dry place protected from light. Keep away from the reach of children.

Packing
Menogia® tablet: Carton of 60 tablets in blister pack.

® Registered Trade Mark

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Manufactured by

Advanced Chemical Industries Limited
7, Hajeegonj Road, Godnyl
Narayangonj, Bangladesh

Popular Pharmaceuticals Ltd. for