

Understands her Need

*Postponement of Menstruation
Arrest Dysfunctional Uterine Bleeding
Treat Amenorrhea
Treat Endometriosis
Relief PMS*



NOREGYN 5mg
Tablet
[Norethisterone Tablets BP]

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Understands Her Need

- TIME TESTED PROGESTERONE
- PROVEN SAFETY AND EFFICACY
- QUALITY WITH ECONOMY

FOR POSTPONEMENT OF MENSTRUATION

One tablet Noregyn 3 times daily beginning about 3 days before the expected menstruation for not longer than 10 to 14 days.

24	25	26	27	28	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	
																			BLEEDING AFTER NOREGYN									

Postponed Periods

TO ARREST DYSFUNCTIONAL UTERINE BLEEDING (DUB)

One tablet Noregyn 3 times daily over 10 days leads to the arrest of uterine bleeding not associated with organic lesions within 1 to 3 days.

To prevent the recurrence of dysfunctional bleeding, 1 tablet Noregyn 2 to 3 times daily from 19th to 26th day of the cycle.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28

TO TREAT PRIMARY AND SECONDARY AMENORRHEA

One tablet Noregyn 2 to 3 times daily from the 19th to the 26th day of the cycle.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
ENDOMETRIAL PRIMING WITH AN ESTROGEN																											

Treatment should be continued for over at least 2 to 3 cycles.

TO RELIEF PREMENSTRUAL SYMPTOMS (PMS): One tablet 2 to 3 times daily from the 19th to 26th day of the cycle.

TO TREAT ENDOMETRIOSIS: One tablet two times daily beginning between 1st - 5th day of cycle. Increase to 2 tablets twice daily in the event of spotting. Duration of treatment at least 4 to 6 months.

Brief Prescribing information:

Composition: Noregyn tablet contains Norethisterone 5 mg. **Pharmacodynamic Properties:** Complete transformation of the endometrium can be achieved with 80 to 150mg norethisterone, spread over 8 to 10 days, in adequately estrogen-primed castrated women. This amount is sufficient to bring the endometrium up to the condition which it is normally in at the end of the luteal phase. The menstruation-like withdrawal bleeding begins almost invariably 2 to 4 days after discontinuation of the medication. Norethisterone has an inhibitory effect on the secretion of gonadotropins in the anterior lobe of the pituitary. Norethisterone increases the basal body temperature: 10 mg norethisterone daily increases it by about 0.5°C. In addition to the transformationary action norethisterone also has a styptic effect. A local influence on the endometrium leads to the cessation of dysfunctional bleeding. **Pharmacokinetic properties:** Absorption: Orally administered norethisterone is absorbed over a wide dose range. Peak serum concentrations of about 16 ng/mL are reached within about 1.5 hours of administration of one 5 mg tablet Noregyn. Due to a marked first-pass effect, the bioavailability of norethisterone after an oral dose is about 64%. **Distribution:** Norethisterone is bound to serum albumin and to sex hormone binding globulin (SHBG). Only about 3 to 4% of the total serum drug concentration is present as free steroid, about 35% and 61% is bound to SHBG and albumin, respectively. Norethisterone is secreted into breast milk. **Metabolism:** Norethisterone is mainly metabolised by saturation of the double bond in ring A and the reduction of the 3-keto group to a hydroxyl group, followed by conjugation to the corresponding sulphates and glucuronides. **Elimination:** Norethisterone is not excreted unchanged to a significant extent. Predominantly A-rings-reduced and hydroxylated metabolites, as well as their conjugates (glucuronides and sulphates), are excreted via urine and faeces at a ratio of about 7:3. **Steady-state conditions:** During multiple-dose daily administration with norethisterone, an accumulation of the drug is unlikely because of the relatively short half-life of the drug. If, however, SHBG-inducing agents such as ethinylestradiol are co-administered, an increase in norethisterone serum levels can occur because of the binding of norethisterone to SHBG. **Contra-Indications:** Noregyn should not be used in the presence of known or suspected pregnancy, Lactation, Active thromboembolic processes or a history thereof, 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 tumours (benign or malignant) Known or suspected sex hormone-dependent malignancies, Hypersensitivity to the active substance or to any of the excipients. Immediately discontinue the use of Noregyn if any of the conditions appear during its use. **General side effects:** It is unusual for people to experience side effects when taking normal doses of Noregyn. Side effects that have been reported include: feeling slightly sick (nausea), worsening of epilepsy, worsening of migraine, skin problems **Special precautions** Diabetes mellitus must be actively excluded as this disease requires careful supervision. 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. **Interaction with other medicines and other forms of 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), giseofolol, oxcarbazepine, and rifabutin are also suspected. **Presentation:** Noregyn 5mg Tablet 3 x 10's blister pack.

“Medicines For All”



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