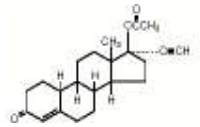
Penorit® Tablets

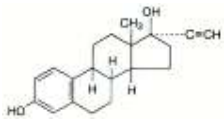
(Norethisterone Acetate + Ethinyloestradiol)

Composition:
Each sugar coated tablet contains:
Norethisterone Acetate USP……10mg
Ethinyloestradiol USP……0.02mg

Description:
Each sugar coated tablet contains:
Norethisterone Acetate (17œ-ethinyl-19-nortestosterone acetate), 10mg
Ethinyloestradiol 17œ-ethinyl-1,3,5(10)-estratriene-3, 17ß-diol), .02mg



Norethisterone acetate
Molecular Weight: 340.46



Thinyloestradiol C22H28O3
C20H24O2 Molecular Weight: 296.40

Clinical Pharmacology:
Combination oral contraceptives act by suppression of gonadotropins. Although the primary mechanism of this action is inhibition of ovulation, other alterations include changes in the cervical mucus (which increase the difficulty of sperm entry into the uterus) and the endometrium (which reduce the likelihood of implantation)

Pharmacokinetics:
The pharmacokinetic of Norethisterone Acetate and Ethinyloestradiol tablets have not been characterized; however, the following pharmacokinetic information regarding Norethisterone Acetate and Ethinyloestradiol is taken from the literature

Absorption:
Norethisterone acetate appears to be completely and rapidly deacetylated to Norethisterone after oral administration, since the disposition of Norethisterone acetate is indistinguishable from that of orally administered Norethisterone. Norethisterone acetate and Ethinyloestradiol are subject to first-pass metabolism after oral dosing, resulting in an absolute bioavailability of approximately 64% for Norethisterone and 43% for Ethinyloestradiol

Distribution:
Plasma protein binding of both steroids is extensive (>95%); Norethisterone binds to both albumin and sex hormone binding globulin, whereas Ethinyloestradiol binds only to albumin

Metabolism:
Norethisterone undergoes extensive biotransformation, primarily via reduction, followed by sulfate and glucuronide conjugation. The majority of metabolites in the circulation are sulfates, with glucuronides accounting for most of the urinary metabolites. A small amount of Norethisterone acetate is metabolically converted to Ethinyloestradiol. Ethinyloestradiol is also extensively metabolized, both by oxidation and by conjugation with sulfate and glucuronide. Sulfates are the major circulating conjugates of Ethinyloestradiol and glucuronides predominate in urine
The primary oxidative metabolite is 2-hydroxy Ethinyloestradiol, formed by the CYP3A4 isoform of cytochrome P450. Part of the first-pass metabolism of Ethinyloestradiol believed to occur in gastrointestinal mucosa. Ethinyloestradiol may undergo enterohepatic circulation

Excretion:
Norethisterone and Ethinyloestradiol are excreted in both urine and feces, primarily as metabolites

Indications:
Penorit® is a hormone preparation for the treatment of the non-occurrence of menstrual periods in certain cases (secondary amenorrhoea) Treatment with Penorit® should not be carried out until at least 8 weeks have elapsed since the last menstruation and the existence of pregnancy has been ruled out

Contra-indications:
It should not be used in women who currently have the following conditions:

- Thrombophlebitis or thromboembolic disorders
- A past history of deep vein thrombophlebitis or thromboembolic disorders
- Cerebral vascular or coronary artery disease
- Known or suspected carcinoma of the breast
- Carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia
- Undiagnosed abnormal genital bleeding
- Hepatic adenomas or carcinomas

Dosage and direction:
After excluding the existence of pregnancy, 1 tablet of Penorit® is taken with a little fluid on two consecutive days. After 3-6 days on average a menstrual-like bleeding of normal intensity occurs. In some patients 15 days may elapse before bleeding occurs
If this bleeding does not occur, then further diagnostic and therapeutic are required

Warning:
Penorit® may only be used when pregnancy has been ruled out

Precautions:

Nursing Mothers:
Small amounts have been identified in the milk of nursing mothers, and a few adverse effects on the child have been reported, including jaundice and breast enlargement. In addition, oral contraceptives, given in the postpartum period may interfere with lactation by decreasing the quantity and quality of breast milk.

Drug Interactions:
Reduced efficacy and increased incidence of breakthrough bleeding and menstrual irregularities have been associated with concomitant use of rifampin. A similar association though less marked, has been suggested with barbiturates, phenylbutazone, phenytoin sodium, and possibly with griseofulvin, ampicillin and tetracyclines

Adverse reactions:
An increased risk of the following serious adverse reactions has been associated with its use:
Thrombophlebitis, arterial thromboembolism, pulmonary embolism, myocardial infarction, cerebral hemorrhage, cerebral thrombosis, hypertension, gallbladder disease, hepatic adenomas, carcinomas or benign liver tumors

Instruction:
Keep out of reach of children
Avoid exposure to heat light and humidity
Store at 25ºC or below
Improper storage may deteriorate the medicine

How Supplied:
Penorit® tablets in pack of 20's

پینورٹ ٹیبلٹ

(نارتھسٹیرون ایسی ٹیٹ + ایتھی نائل ایسٹراڈائول)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں
ہدایات: بچوں کی پہنچ سے دور رکھیں
دوا کو دھوپ، گرمی اور نمی سے محفوظ ۲۵ ڈگری سینٹی گریڈ
یا اس سے کم درجہ حرارت پر رکھیں ورنہ دوا خراب ہو جائے گی

Manufactured by:
SAMI PHARMACEUTICALS (PVT) LTD.
F-95, S.I.T.E., Karachi-Pakistan