For consumer information only

Epirita®-35

(Cyproterone Acetate & Ethinylestradiol Tablets)

Composition:

Each Film coated Tablet Contains:
Cyproterone Acetate I.P .....2 mg
Ethinylestradiol Tablet I.P... ..... 0.035 mg
Excipients .....q.s.

Clinical Pharmacology:
Cyproterone acetate and Ethinylestradiol is a combination antiandrogen-estrogen for use in Hyperandrogenism and PCOS related conditions also the treatment of androgen-dependent dermatological conditions in females.

Cyproterone Acetate:

- Cyproterone acetate is a steroid compound with potent antiandrogenic, progestogenic and antigonadotrophic activity. It exerts its antiandrogenic effect by blocking androgen receptors. It also reduces androgen synthesis by a negative feedback effect on the hypothalamo-pituitary-ovarian systems.
- Cyproterone acetate has no tendency to reduce SHBG levels. If used alone in women, cyproterone acetate leads to menstrual cycle disturbances which are avoided when combined with ethinyl estradiol.

Ethinylestradiol:

- The estrogen component (ethinylestradiol) of Cyproterone acetate and ethinylestradiol increases levels of sex hormone binding globulin (SHBG) and thus reduces the free circulating plasma levels of androgens. When cyproterone acetate and ethinyl estradiol tablets are administered in a cyclic manner it has the added effect of preventing ovulation and possible conception.
- The components of cyproterone acetate and ethinyl estradiol tablets are rapidly absorbedafteroraladministration.Duetothelongterminalhalf-lifeofcyproterone acetate, a 4-fold increase in plasma levels occurs after 6 to 12 days of daily dosing.

Indications:

For the Management of

- PCOS
- Hirsutism
- Acne
- Alopecia
- Menstrual Abnormalities

Contraindications:

- History of oractual thrombophlebitis or thromboembolic disorders;
- History of oractual cerebrovascular disorders;
- History of oractual myocardial infarction or coronary arterial disease;
- Active liver disease;
- Previous or existing liver tumours (benign or malignant);
- History of cholestatic jaundice;
- Known or suspected carcinoma of the breast.

Warning and Precaution:

Warning

Cyproterone/ethinylestradiol, like all estrogen/progestogen combinations, is associated with an increased risk of venous thromboembolism (VTE) compared with no use.

Precautions:

Physical Examination and Follow-up: The first follow-up visit should be done 3 months after the initial prescription. Thereafter, examinations should be performed at regular intervals during treatment and more frequently for those patients at greater risk for adverse effects.
Hepatic Function: If there is a clear-cut history of cholestatic jaundice, especially if it occurred during pregnancy, other methods of treatment should be prescribed.

Drug Interaction:

The concurrent administration of estrogen/progestogen combinations with other drugs may result in an altered response to either agent. Estrogen/progestogen combinations like cyproterone acetate and ethinyl estradiol tablets may affect the metabolism of certain other drugs. Accordingly, plasma and tissue concentrations may either increase (eg, cyclosporine) or decrease (eg, lamotrigine) . It is important to ascertain all drugs that a patient is taking, both prescription and non-prescription, before estrogen/progestogen therapy is prescribed.

Adverse Effects:

- Thrombophlebitis
- Arterial and venous thromboembolism
- Pulmonary embolism
- Mesenteric thrombosis
- Neuro-ocular lesions (eg, retinal thrombosis and optic neuritis)

Route of Administration: Oral.

Type of Tablet: Film coated tablet.

Dosage: As directed by Physician/Gynecologist.

Storage: Store Protected from light & Moisture at a temperature not exceeding 30˚C.
Keep the medicine out of reach of children.

SCHEDULE H PRESCRIPTION DRUG-CAUTION: Not to be sold by retail without the prescription of a Registered Medical Practitioner.

Presentation: Epirita-35 is available as 1×21 Tablets/Strip.

Marketed by:

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Soothing Touch of Life...
(An ISO 9001:2015 Certified Co.)
www.epionepharma.com

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