HERFACE

For the use of Registered Medical Practitioner or Hospital or a Laboratory only

Abbreviated Prescribing information for HERFACE (Cyproterone acetate 2mg and Ethinylestradiol 35 microgram) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Cyproteron acetate: ynthetic steroidal antiandrogen drug with additional progesterone and antigonadotropic activity. Ethinyl estradiol: major endogenous hormone in humans. It blocks androgen-receptors. It also reduces androgen synthesis both by negative feedback effect on the hypothalamo-pituitiary-ovarian systems and by the inhibition of androgen-synthesising enzymes. **INDICATIONS**: for use in women only for the treatment of (a) severe acne, refractory to prolonged oral antibiotic therapy; (b) moderately severe hirsutism. Although it also acts as an oral contraceptive, it should not be used in women solely for contraception, but should be reserved for those women requiring treatment for the androgen dependent conditions described. **DOSAGE AND ADMINISTRATION**: contraception: First treatment course: One tablet daily for 21 days, starting on the first day of the menstrual cycle. Subsequent courses: Each subsequent course is started after 7 tablet-free days have followed the preceding course. Post-partum and post-abortum use: After pregnancy, it can be started 21 days after a vaginal delivery, provided that the patient is fully ambulant and there are no puerperal complications. Complete remission of acne is to be expected in nearly all cases, often within a few months. **CONTRAINDICATIONS**: Existing or a history of confirmed venous thromboembolism (VTE), major surgery with prolonged immobilization, Existing or previous arterial thrombotic or embolic processes, Conditions which predispose to thromboembolism, Severe and/or multiple risk factor(s) for venous or arterial thrombosis, Severe or uncontrolled hypertension or hypertension associated with vascular disease, History of migraine with focal neurological symptoms, Severe diabetes mellitus with vascular changes, Presence or history of severe hepatic disease, Presence or history of liver tumours, Current or history of breast cancer, Known or suspected pregnancy, Breast-feeding, Hypersensitivity to the active substances or to any of the excipients. It is not for use in men. **WARNINGS AND PRECAUTIONS:** Conditions which require strict medical supervision: Diabetes mellitus, porphyria, clinical depression, obesity, migraine, cardiovascular diseases, chloasma. Circulatory disorders, Arterial thromboembolic-related condition, Breast cancer, Cervical Cancer, Liver Cancer, Known hyperlipidaemias, Disturbances of liver function, Menstrual Changes. **DRUG INTERACTIONS**: Hepatic enzyme inducers, Non-enzyme inducing antibiotics, Oral contraceptives and oestrogen/progestogen combinations. **ADVERSE REACTIONS**: contact lens intolerance, nausea, abdominal pain, vomiting, diarrhea, Exacerbation of hereditary angioedema, weight increased, weight decreased, fluid retention, hypertriglyceridemia, headache, migraine, exacerbation of chorea, Crohn's disease, ulcerative colitis, depressed mood, mood altered, libido decreased, libido increased, breast pain, breast tenderness, breast hypertrophy, vaginal discharge, breast discharge, reduced menstrual flow, spotting, breakthrough bleeding and missed withdrawal bleeding, post pill amenorrhoea, rash, urticarial, erythema nodosum, erythema multiforme and strokes.

MARKETED BY:

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(Additional information is available on request)