

Frewil™

Cyproterone Acetate 2 mg and Ethinylestradiol Tablets 0.035 mg

Therapeutic indications: For the treatment of Androgen-dependent diseases in women, such as acne, alopecia and mild forms of hirsutism.

Dosage and Administration: The dose regimen of Frewil™ is similar to the usual regimen of most of the combined oral contraceptives. Thus, the same administration rules must be considered. Tablets must be taken in the order directed on the package every day at about the same time with some liquid as needed. One tablet is to be taken daily for 21 consecutive days. Each subsequent pack is started after a 7-day tablet-free interval.

Use in Special Populations: Yanci is only indicated after menarche and not after menopause. It is not recommended in nursing mother. **Contraindications:** Presence or a history of venous or arterial thrombotic/thromboembolic events (e.g. deep venous thrombosis, pulmonary embolism, myocardial infarction) or of a cerebrovascular accident, migraine with aura, diabetes mellitus, severe hepatic disease or liver tumors, severe renal insufficiency or acute renal failure, sex-steroid influenced malignancies, undiagnosed vaginal bleeding, known or suspected pregnancy and hypersensitivity to the active substances or to any of the excipients. **Drug Interactions:** Enzyme-inducers and antibiotics e.g. Phenytoin, Barbiturates, Primidone, Carbamazepine, Rifampicin, HIV protease (e.g. Ritonavir) and non-nucleoside reverse transcriptase inhibitors (e.g. Nevirapine) and possibly also Oxcarbazepine, Topiramate, Felbamate, Griseofulvin and products containing St. John's wort can increase the hepatic metabolism and diminish the efficacy of Frewil™. **Warnings and precautions:** In women with history of smoking, diabetes, overweight, high blood pressure, heart valve disorder or a certain heart rhythm disorder, superficial phlebitis, varicose veins, , migraine, epilepsy, immediate family has had breast cancer, liver or gallbladder disease, Crohn's disease or ulcerative colitis, SLE, HUS, sickle cell disease and chloasma.

Adverse reactions: Common (≥1/100): Nausea, abdominal pain, breast pain and tenderness, headache, emotional lability, depression/ depressive mood decrease and weight increased. **Uncommon (≥1/1000 and <1/100):** Vomiting, diarrhea, fluid retention, migraine, decreased libido, breast hypertrophy, rash and urticaria. **Rare (≥1/1000):** Contact lens intolerance, hypersensitivity, weight decreased, libido increased, vaginal discharge, breast discharge, erythema nodosum and erythema multiforme.

Dosage Forms and Strengths: Blister pack of 21 tablets. Each film coated tablet contains Cyproterone Acetate IP 2 mg and Ethinylestradiol IP 0.035 mg.

Storage: Store below 30°C.

Manufactured in India by: Mylan Laboratories Ltd, Plot No:- 20 & 21, Pharmez, Sarkhej-Bavla, National Highway No.8- A, Near Village Matoda, Tal.-Sanand, Dist.-Ahmedabad – 382 213. Gujarat, India.

Marketed by: Mylan Pharmaceuticals Private Limited, Plot No. 1-A/2, MIDC Industrial Estate, Taloja, Panvel, District: Raigad, Maharashtra - 410 208, India

Abbreviated Prescribing Information Version 12/2016.

Please refer to the full Prescribing Information before prescribing Frewil™ , available on request from Mylan Pharmaceuticals Private Limited, 10th Floor, Prestige Platina, Block 3, Kadubeesanahalli Village, Varthur Hobli, Outer Ring Road, Bangalore 560 087