ginette35

99332230

To be sold by retail on the prescription of RMP only

Ethinylestradiol And Cyproterone Acetate Tablets

ginette35

QUALITATIVE AND QUANTITATIVE COMPOSITION

GINETTE 35

Each film-coated tablet contains
Ethinylestradiol IP ..... 0.035 mg
Cyproterone acetate IP ..... 2 mg

Colours: Quinoline Yellow Lake & Titanium Dioxide IP.

DOSAGE FORM AND STRENGTH

Cyproterone acetate 2 mg and Ethinylestradiol 0.035 mg tablets for oral use.

CLINICAL PARTICULARS

Therapeutic Indications

GINETTE 35 is indicated for the treatment of androgen-dependent disease in women such as acne, alopecia and mild form of hirsutism.

Posology and Method of Administration

GINETTE 35 inhibits ovulation and, thereby, prevents conception. Patients who are using **GINETTE 35** should not, therefore, use an additional hormonal contraceptive, as this will expose the patient to an excessive dose of hormones and is not necessary for effective contraception.

First Treatment course

One tablet daily for 21 days following the arrows, starting on the first day of the menstrual cycle (the first day of menstruation counting as day 1).

Subsequent Courses

Each subsequent course is started after 7 tablet-free days have followed the preceding course. When the contraceptive action of **GINETTE 35** is also to be employed, it is essential that the above instructions be rigidly adhered to. Should bleeding fail to occur during the tablet-free interval, the possibility of pregnancy must be excluded before the next pack is started.

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Duration of Use

Time to relief of symptoms is at least three months. The need to continue treatment should be evaluated periodically by the treating physician.

Contraindications

- Concomitant use with another hormonal contraceptive.
- Venous thrombosis present or in history (e.g. deep venous thrombosis, pulmonary embolism)
- Arterial thrombosis present or in history (e.g. myocardial infarction) or prodromal conditions (e.g. angina pectoris and transient ischaemic attack)
- Presence or history of cerebrovascular accident
- The presence of a severe or multiple risk factor(s) for venous or arterial thrombosis such as:
  - diabetes mellitus with vascular symptoms
  - severe hypertension
  - severe dyslipoproteinaemia
- Hereditary or acquired predisposition for venous or arterial thrombosis, such as activated protein C (APC) resistance, antithrombin-III-deficiency, protein C deficiency, protein S deficiency, hyperhomocysteinaemia and antiphospholipid-antibodies (anticardiolipin-antibodies, lupus anticoagulant).
- History of migraine with focal neurological symptoms
- Presence or history of severe hepatic disease e.g. active viral hepatitis and severe cirrhosis, as long as liver function values have not returned to normal.
- Presence or history of liver tumours (benign or malignant)
- Current or history of breast cancer
- Known or suspected pregnancy
- Breastfeeding
- Hypersensitivity to the active substances or to any of the excipients
- Concomitant use with the medicinal products containing ombitasvir / paritaprevir / ritonavir or dasabuvir.

CPA+EE is not for use in men.

Undesirable Effects

The most commonly reported adverse reactions with CPA+EE are nausea, abdominal pain, increased weight, headache, depressed mood, altered mood, breast pain, breast tenderness. They occur in ≥ 1 % of users.
There is an increased risk of thromboembolism for all women who use CPA+EE.

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You can also e-mail us at
specialities@cipla.com

Adverse Events Reported in Clinical Trials

Common (1/100 to <1/10) - Nausea, Abdominal pain, Weight increased, Headache, Depressed mood, Mood altered, Breast pain, Breast tenderness

Uncommon (1/1000 to <1/100) - Vomiting, Diarrhoea, Fluid retention, Migraine, Libido decreased, Breast hypertrophy, Rash, Urticaria

Rare (≥1/10,000 to < 1/1000) - Contact lens intolerance, Hypersensitivity, Weight decreased, Libido increased, Vaginal discharge, Breast discharge, Erythema nodosum, Erythema multiforme, Thromboembolism

Adverse Events Reported Post-Marketing - Crohn's disease, ulcerative colitis, exacerbation of hereditary angio-oedema, hypertriglyceridaemia, exacerbation of chorea, liver function disturbances, reduced menstrual flow, spotting, breakthrough bleeding and missed withdrawal bleeding, post-pill amenorrhoea, chloasma, increase in blood pressure.

Post-marketing reports of severe depression (including very rare reports of suicidal ideation or behaviour) in patients using CPA+EE have been received. However, a causal relationship between clinical depression and CPA+EE has not been established.

An increased risk of arterial and venous thrombotic and thrombo-embolic events, including myocardial infarction, stroke, transient ischemic attacks, venous thrombosis and pulmonary embolism has been observed in women using CHCs.

The following serious adverse events have been reported in women using CHCs.

- Venous thromboembolic disorders
- Arterial thromboembolic disorders
- Hypertension
- Liver tumours
- Occurrence or deterioration of conditions for which association with COC use is not conclusive: Crohn's disease, ulcerative colitis, epilepsy, uterine myoma, porphyria, systemic lupus erythematosus, herpes gestationis, Sydenham's chorea, haemolytic uremic syndrome, cholestatic jaundice;
- Chloasma;
- Acute or chronic disturbances of liver function may necessitate the discontinuation of COC use until markers of liver function return to normal.
- In women with hereditary angioedema exogenous oestrogens may induce or exacerbate symptoms of angioedema.

The frequency of diagnosis of breast cancer is very slightly increased among COC users. As breast cancer is rare in women under 40 years of age the excess number is small in relation to the overall risk of breast cancer. Causation with COC or CPA+EE use is unknown.

Reporting of side effects

If you experience any side-effects, talk to your doctor or pharmacist or write to drugsafety@cipla.com. You can also report side effects directly via the national pharmacovigilance program of India by calling on 1800 180 3024 or you can report to Cipla Ltd on 18002677779. By reporting side effects, you can help provide more information on the safety of this product.

Overdose

Overdose may cause nausea, vomiting and withdrawal bleeding. Withdrawal bleeding may even occur in girls before their menarche, if they accidentally take the medicinal product. There are no specific antidotes and further treatment should be symptomatic.

DETAILS OF MANUFACTURER

Manufactured in India by: Synokem Pharmaceuticals Ltd.
Plot No.: 56-57, Sector-6A, I.I.E (SIDCUL), Ranipur (BHEL),
Haridwar-249403 (Uttarakhand)

2010020555

Marketed by

Marketed by **CIPLA LTD.**
Registered Office:
Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg,
Lower Parel, Mumbai - 400 013, INDIA

DETAILS OF PERMISSION OR LICENCE NUMBER WITH DATE

M.L. 27/UA/SC/P-2018 dated: 29.07.2020

DATE OF REVISION

31/07/2020

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Name :

Address :

Contact No. :

Doctor's name :

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