

Famylette®

Desogestrel Tablets BP

Therapeutic indications: For the prevention of pregnancy.

Dosage and Administration: Tablets must be taken every day at about the same time so that the interval between two tablets always is 24 hours. Tablet-taking has to start on day 1 of the woman's natural cycle (day 1 is the first day of her menstrual bleeding). Starting on days 2-5 is allowed, but during the first cycle a barrier method is recommended for the first 7 days of tablet-taking. Following delivery, the woman should be advised to start any day between days 21 to 28 after delivery. For the missed tablets and in abortions please refer to the full prescribing information. Special warnings and precautions: Famylette® should be prescribed with precaution in women having breast cancer, liver cancer, ever had a thrombosis, diabetes, epilepsy, tuberculosis, high blood pressure, chloasma. Decreased Bone Mass: Estrogens are important to maintain the strength of bones. During the use of Famylette®, the concentration in blood of the natural estrogen, estradiol, is comparable to the concentration seen in the first half of the natural cycle but is decreased in comparison with the second half of the natural cycle. It is not known whether this has an effect on the strength of the bones. Drug-Drug Interactions: Some medicines may stop Famylette® from working properly. These include medicines used for the treatment of epilepsy (e.g. primidone, phenytoin, carbamazepine, oxcarbazepine, felbamate and phenobarbital), tuberculosis (e.g. rifampicin, rifabutin), HIV infections (e.g. ritonavir), or other infectious diseases (e.g. griseofulvin), stomach upset (medical charcoal) and depressive moods (the herbal remedy St. John's wort).

Pregnancy: Do not use Famylette® if woman is pregnant, or think woman may be pregnant. **Breast-feeding:** Famylette® may be used while woman is breast-feeding. Famylette® does not influence the production or the quality of breast milk. However, a small amount of the active substance of Famylette® passes over into the milk. The health of children breast-fed for 7 months whose mothers were using Famylette® has been studied up to 2.5 years of age. No effects on the growth and development of the children were observed. Adverse reactions: Common (occurring in more than one per 100 users) are mood altered, decreased sexual drive (libido), headache, nausea, acne, breast pain, irregular or no periods, weight increase.

Uncommon (occurring in more than one per 1000 users but not more than one per 100 users) are Infection of the vagina, difficulties in wearing contact lenses, vomiting, hair loss, painful periods, ovarian cysts, tiredness. Rare (occurring in less than one per 1000 users) are rash, hives, painful blue-red skin lumps (erythema nodosum) (these are skin conditions).

Dosage Forms and Strengths: Each tablet of Famylette® contains active substance as Desogestrel (75 microgram) and other ingredients include colloidal silicon dioxide; DL- alpha- Tocopherol; stearic acid; anhydrous lactose, Potato starch GMO free starch, Polyvinyl pyrrolidone (Kollidon 30).

Storage: Store below 30°C, protect from light and moisture.

Manufactured 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 Famycept®, available on request from Mylan Pharmaceuticals Private Limited, 10th Floor, Prestige Platina, Block 3, Kadubeesanahalli Village, Varthur Hobli, Outer Ring Road, Bangalore 560 087.