Descon®

Desogestrel 0.15mg and Ethinylestradiol 0.03mg Tablets USP

Therapeutic indications: For use as oral contraceptive for women.
Dosage and Administration: Tablet-taking has to start on day 1of the woman's natural cycle (i.e. the first day of her menstrual bleeding). One tablet is to be taken daily for 21consecutive days. During the next 7 days do not take tablets. A period should begin during these 7 days (the withdrawal bleed). Usually it will start on day 2-3 after the last Descon®

tablet. Start taking next pack on the 8th day even if period continues. This means that the new pack usage starts on the same day of the week and also the women will have withdrawal bleed on about the same days, each month. Please refer to the full prescribing information for management of missed tablets.

Used under close observation: Smoke, 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. **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 with blood vessel damage, severe hepatic disease or benign or malignant 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 increase the hepatic metabolism and diminish the efficacy of Descon®.

Adverse reactions: Most common (≥1/100 to< 1/10): Spotting or bleeding between menstrual periods, nausea, breast tenderness and headache, emotional lability, depression/ depressive mood decrease and loss of libido. Uncommon (1/1,000 to<1/100): Paresthesia, vertigo, Venous and arterial thromboembolic events and rarely erythema multiforme.

Dosage Forms and Strengths: Each uncoated Tablet: Desogestrel BP 0.15 mg, Ethinylestradiol IP 0.03 mg and Excipients q.s.

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