

Yanci®

Drospirenone 3mg and Ethinylestradiol 0.03mg Tablets IP

Therapeutic indications: For use as oral contraceptive for women.

Dosage and Administration: Tablet-taking has to start on day 1 of the woman's natural cycle (i.e. the first day of her menstrual bleeding). One tablet is to be taken daily for 21 consecutive 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 Yanci® 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.

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 increase the hepatic metabolism and diminish the efficacy of Yanci®. **Warnings and Precautions:** Yanci® must be used with caution in women with cardiovascular disease risk factors, hyperkalemia, high blood pressure, gallbladder disease, headache and bleeding irregularities.

Adverse reactions: Most common ($\geq 1/100$ 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: Drospirenone IP 3 mg, Ethinylestradiol IP 0.03 mg and Excipients q.s.

Shelf Life: 2 years

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