

DROSPERT

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for DROSPERT (Drospirenone Tablets 4 mg with Inert Tablets)

[Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action: Drospirenone progestin-only oral contraceptive lowers the risk of becoming pregnant primarily by suppressing ovulation.

INDICATIONS: Drospirenone is a Progestin intended for its use by females of reproductive potentials to prevent pregnancy.

DOSAGE AND ADMINISTRATION: Drospirenone is dispensed in a blister card. Drospirenone should be started using a Day 1 start.

CONTRAINDICATION: Drospirenone is contraindicated in females with the following conditions: Renal impairment, Adrenal insufficiency, presence or history of cervical cancer or progestin sensitive cancers, Liver tumors, benign or malignant, or hepatic impairment, Undiagnosed abnormal uterine bleeding. The combination of DROSPERT with reversible MAO-A inhibitors (e.g. moclobemide) or the reversible non-selective MAO-inhibitor linezolid is contraindicated due to the risk of onset of a serotonin syndrome.

WARNINGS & PRECAUTIONS: For use of Drospirenone with Patients with Hyperkalemia, Thromboembolic Disorders, Bone loss, Cervical cancer, Ectopic Pregnancy, risk with Hyperglycemia in patient with Diabetes, Bleeding Irregularities and Amenorrhea, Depression.

DRUG INTERACTIONS: Effects of Other Drugs on Hormonal Contraceptives are Substances decreasing the systemic concentrations of hormonal contraceptives (HCs) and potentially diminishing the efficacy of HCs: Drugs or herbal products that induce certain enzymes, including cytochrome P450 3A4 (CYP3A4), may decrease the systemic concentrations of HCs and potentially diminish the effectiveness of HCs or increase breakthrough bleeding. Some drugs or herbal products that may decrease the effectiveness of HCs include efavirenz, phenytoin, barbiturates, carbamazepine, bosentan, felbamate, griseofulvin, oxcarbazepine, rifampicin, rifabutin, rufinamide, aprepitant, and products containing St. John's wort. Substances increasing the systemic concentrations of hormonal contraceptives (HCs), Influence of Drospirenone on other Medicinal Products: Based on reported in vitro studies and in vivo interaction studies in female volunteers using omeprazole, simvastatin and midazolam as marker substrate, an interaction of drospirenone with the metabolism of other active substances is unlikely, Potential to increase serum potassium concentration: There is a potential for an increase in serum potassium concentration in females taking Drospirenone with other drugs that may increase serum potassium concentration (for example, ACE inhibitors, angiotensin-II receptor antagonists, potassium-sparing diuretics, potassium supplementation, heparin, aldosterone antagonists, and NSAIDS).

ADVERSE REACTIONS: Most common are acne, menstrual cramps, headache, nausea, breast pain and tenderness, severe vaginal bleeding, weight gain, less sexual desire. Serious side effects, including hyperkalemia, palpitation, shortness of breath, blood clot forming in blood vessels (thromboembolism problems), Bone loss, cervical cancer, Ectopic pregnancy, risk of high blood sugar levels in people with diabetes and depression.

MARKETED BY:



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IN/ DROSPERT 4 mg/NOV-21/01/ABPI

(Additional information is available on request)