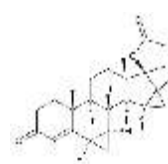


Rx DROSPIRENONE

(ETHINYL ESTRADIOL/DROSPIRENONE - ORAL (ETH-in-il ess-tra-DYE-ole/droh-SPYE-re-none))



GENERIC NAME: ETHINYL ESTRADIOL/DROSPIRENONE - ORAL (ETH-in-il ess-tra-DYE-ole/droh-SPYE-re-none)

DRUG INTERACTIONS

Certain drugs can decrease the effectiveness of combination-type birth control pills by decreasing the amount of birth control pill hormones in your system (impaired enterohepatic recirculation or hepatic induction). This can result in pregnancy. Consult your doctor or pharmacist for details. Drugs that may cause this effect include: many antibiotics (e.g., cephalosporins, chloramphenicol, macrolides, penicillins, tetracyclines, sulfas), aprepitant, bexarotene, bosentan, dapson, griseofulvin, certain HIV protease inhibitors (e.g., amprenavir, nelfinavir, ritonavir), modafinil, nevirapine, rifamycins (e.g., rifampin), many seizure medications (e.g., barbiturates, carbamazepine, phenytoin, primidone, topiramate), St. John's wort. Ask your doctor if you should use additional reliable birth control methods while taking any of the drugs mentioned above while also taking birth control pills. Before taking this medication, tell your doctor of all prescription and nonprescription medication you may use, especially of: ACE inhibitors (e.g., enalapril, lisinopril), angiotensin receptor blockers (e.g., losartan, valsartan), potassium-sparing "water pills" (e.g., spironolactone, triamterene), potassium supplements, heparin, NSAIDs (e.g., ibuprofen, naproxen), atorvastatin, cyclosporine, corticosteroids (e.g., prednisone, prednisolone) theophylline, ascorbic acid (vitamin C), acetaminophen, morphine, temazepam, clofibrac acid. This product can affect the result of certain lab tests (e.g., liver function tests, blood tests). Make sure laboratory personnel and your doctors know you use this drug. Do not start or stop any medicine without doctor or pharmacist approval.

USES

This combination medication is used to prevent pregnancy. This medication does not protect you or your partner against sexually transmitted diseases (e.g., HIV, gonorrhea).

OTHER USES

This drug may also be used to regulate your menstrual cycle.

HOW TO USE

Take this medication by mouth once daily, or as directed by your doctor. The manufacturer recommends that you take this product after your evening meal or at bedtime to help you remember to take it and to minimize any stomach upset or nausea you may have. You may, however, choose to take this medication at another time of the day instead. No matter what dosing schedule you use, it is important to take this medication at the same time each day. It is recommended to start taking this medication on the first day of your period (menstrual cycle). If it is not possible to start this treatment at the start of your period, consult the product information and/or your doctor or pharmacist for proper instructions. It is recommended that you use an alternative method of birth control during the first week of taking this medication until the full benefit of this drug takes effect.

SIDE EFFECTS

Nausea, vomiting, headache, diarrhea, bleeding between menstrual periods (spotting), weight gain, acne, stomach cramps, rash, swelling or bloating, skin spots, breast tenderness, or difficulty wearing contact lenses may occur. If any of these effects persist or worsen, notify your doctor promptly. Tell your doctor immediately if any of these serious side effects occur: dizziness, flu-like symptoms (e.g., fever, cough, unusual weakness/fatigue, sore throat, muscle aches), mental/mood changes, trouble sleeping, hair loss, vaginal infections. Tell your doctor immediately if any of these unlikely but serious side effects occur: severe headache, pain in the lower legs or groin, trouble breathing, chest pain, vision changes, severe stomach pain, one-sided weakness, yellowing eyes or skin, lumps in the breast. If you notice any other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS

Tell your doctor your medical history, especially of: heart problems, stroke, gallbladder disease, diabetes, high cholesterol or triglyceride levels, high blood pressure, migraines, seizures, irregular vaginal bleeding, depression, any allergies. This medication is not recommended for use if you have the following medical conditions: liver problems, kidney or adrenal gland problems, history of blood clots (thrombophlebitis), blood vessel problems (e.g., cerebral vascular disease, coronary artery disease), history of certain

cancers (especially endometrial or breast cancer), heavy smoking (especially if older than 35 years of age). If you are near-sighted or wear contact lenses, you may develop vision problems or have trouble wearing your contact lenses. Contact your eye doctor if this occurs. If you stop taking this birth control medicine and want to become pregnant, it may take a longer time than is usually seen with women not taking birth control medicine. Consult your doctor. Do not smoke cigarettes. Birth control pills combined with smoking cigarettes, especially in women older than 35 years of age, puts you at a much higher risk of developing serious health problems than with birth control pills alone. Consult your doctor or pharmacist for more information. If you will be having surgery, be confined to a chair or bed for a long period of time (e.g., a long plane flight), or have recently delivered a baby, notify your doctor beforehand. Special precautions may need to be taken in these circumstances while you are taking this drug. This medication must not be used during pregnancy. If you become pregnant or think you may be pregnant, inform your doctor immediately. This medication passes into breast milk and has had undesirable effects on nursing infants. Consult your doctor before breast-feeding.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include nausea and vomiting.

MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, take the missed dose and resume your usual dosing schedule; this may mean taking two tablets in one day. If you miss two or more doses in a row, use an alternate birth control method (e.g., condoms, spermicides) for at least 7 days and consult the product information or your doctor for a new dosing schedule.

STORAGE

Store at room temperature between 59 and 86 degrees F (15 and 30 degrees C) away from light and moisture.

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



Taj Group of Companies ^{INDIA}

Taj Pharmaceuticals Ltd.

Phone : General EPA BX : 91 - (0)22 - 26374592/92 91,
(0)22 - 26374592/93 91 - (0)22 - 30601000,
Fax : 91-(0)22-26341274

Revised November 2010