Ortho Tri-Cyclen/Ortho-Cyclen (ethinyl estradiol/norgestimate) - Drug Summary

Janssen Pharmaceuticals, Inc.

Related Drug Information ▼

Ortho Tri-Cyclen
(ethinyl estradiol/norgestimate)

BOXED WARNING

Cigarette smoking increases risk of serious cardiovascular (CV) events. Risk increases w/ age (>35 yrs of age) and w/ the number of cigarettes smoked. Contraindicated in women who are >35 yrs of age and smoke.

THERAPEUTIC CLASS

Estrogen/progestogen combination

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Contraception

1 tab qd at the same time each day, for 28 days, then repeat

Start 1st Sunday after menses begin or 1st day of menses

Acne Vulgaris

Moderate Acne in Females Who Desire Oral Contraception:
1 tab qd at the same time each day, for 28 days, then repeat

Start 1st Sunday after menses begin or 1st day of menses

Missed Dose

Miss 1 Active Tab in Weeks 1, 2, or 3:
Take as soon as possible. Continue taking 1 tab qd until the pack is finished

Miss 2 Active Tabs in Weeks 1 or 2:
Take 2 missed tabs as soon as possible and the next 2 active tabs the next day. Continue taking 1 tab qd until pack is finished. Use additional nonhormonal contraception (eg, condom, spermicide) as backup if the patient has intercourse w/in 7 days after missing tabs

Miss 2 Active Tabs in Week 3 or Miss ≥3 Active Tabs in a Row in Weeks 1, 2, or 3:
(Day 1 Start) Throw out the rest of the pack and start a new pack that same day. (Sunday Start) Continue to take 1 tab qd until Sunday, then throw out the rest of the pack and start a new pack that same day. (Day 1 Start/Sunday Start) Use additional nonhormonal contraception as backup if the patient has intercourse w/in 7 days after missing tabs

Conversions

Switching from Another Oral Contraceptive:
Start on the same day that a new pack of the previous oral contraceptive would have started

Switching from Another Contraceptive Method:
Transdermal Patch/Vaginal Ring/Inj:
Start therapy on the day when next application would have been scheduled

Intrauterine Contraceptive:
Start on the day of removal; if the intrauterine device is not removed on the 1st day of menstrual cycle, additional nonhormonal contraceptive is needed for the first 7 days of the 1st cycle pack

Implant:

Start therapy on the day of removal

PEDIATRIC DOSAGE & INDICATIONS

Contraception

Not indicated for use premenarche; refer to adult dosing

Acne Vulgaris

Moderate Acne in Postpubertal Females ≥15 Years of Age Who Desire Oral Contraception:
1 tab qd at the same time each day, for 28 days, then repeat

Start 1st Sunday after menses begin or 1st day of menses

DOSING CONSIDERATIONS

Adverse Reactions
GI Disturbances: If vomiting/diarrhea occurs w/in 3-4 hrs after taking an active tab, handle this as a missed tab

Other Important Considerations
Starting Therapy after Abortion or Miscarriage:
1st Trimester: May start immediately; if starting therapy immediately, additional contraception is not needed. If therapy is not started w/in 5 days after termination of the pregnancy, use additional nonhormonal contraception for the first 7 days of 1st cycle pack
2nd Trimester: Do not start until 4 weeks after a 2nd trimester abortion or miscarriage

Starting Therapy after Childbirth:
Do not start until 4 weeks after delivery

ADMINISTRATION

Oral route

Take w/o regard to meals.

Sunday Start Regimen
Use additional nonhormonal contraception for the first 7 days of 1st cycle pack.

HOW SUPPLIED

Tab: (Ethinyl Estradiol [EE]/Norgestimate) 0.035mg/0.18mg, 0.035mg/0.215mg, 0.035mg/0.25mg

CONTRAINDICATIONS

High risk of arterial/venous thrombotic diseases (eg, smoking [if >35 yrs of age], presence/history of deep vein thrombosis [DVT]/pulmonary embolism [PE], inherited or acquired hypercoagulopathies, cerebrovascular disease, coronary artery disease [CAD], thrombogenic valvular/ thrombogenic rhythm diseases of the heart [eg, subacute bacterial endocarditis w/ valvular disease or A-fib], uncontrolled HTN, diabetes mellitus [DM] w/ vascular disease, headaches w/ focal neurological symptoms or migraine headaches w/ aura [women >35 yrs of age w/ any migraine headaches]), benign/malignant liver tumors, liver disease, undiagnosed abnormal uterine bleeding, pregnancy, presence/history of breast cancer or other estrogen- or progestin-sensitive cancer.

WARNINGS/PRECAUTIONS

D/C if an arterial thrombotic event or venous thromboembolic event (VTE) occurs. D/C if there is unexplained loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions; evaluate for retinal vein thrombosis immediately. If feasible, d/c at least 4 weeks before and through 2 weeks after major surgery or other surgeries known to have an elevated risk of VTE as well as during and following prolonged immobilization. In women who are not breastfeeding, initiate therapy no earlier than 4 weeks after delivery; risk of postpartum VTE decreases after the 3rd postpartum week, whereas the risk of ovulation increases after the 3rd postpartum week. Increased risk of VTE and arterial thromboses (eg, strokes, MI). Caution w/ CV disease risk factors. D/C if jaundice develops. May increase risk of developing hepatocellular carcinoma. Increased BP reported; d/c if BP rises significantly. May worsen existing gallbladder disease. May increase risk of cholestasis in women w/ history of pregnancy-related cholestasis. May increase risk of cervical cancer or intraepithelial neoplasia, and gallbladder disease. May decrease glucose tolerance. Consider alternative contraception w/ uncontrolled dyslipidemia. Increased risk of pancreatitis w/ hypertriglyceridemia or family history of hypertriglyceridemia. Evaluate the cause of new headaches that are recurrent, persistent, or severe, and d/c if indicated; consider discontinuation in the case of increased frequency or severity of migraine during use. Unscheduled bleeding and spotting may occur; rule out pregnancy or malignancy. May cause amenorrhea; if scheduled bleeding does not occur, consider possibility of pregnancy. Administration of therapy to induce withdrawal bleeding should not be used as a test for pregnancy. Caution w/ history of depression; d/c if depression recurs to a serious degree. May interfere w/ lab tests (eg, coagulation factors, lipids, glucose tolerance, binding proteins). Chloasma may occur, especially w/ history of chloasma gravidarum; avoid exposure to the sun or UV radiation. **EE:** In women w/ hereditary angioedema, may induce/exacerbate angioedema.

ADVERSE REACTIONS

Irregular uterine bleeding, nausea, headache/migraine, abdominal/GI pain, vaginal infection, genital discharge, breast issues (eg, breast pain, discharge, and enlargement), mood disorders.

DRUG INTERACTIONS

Drugs or herbal products that induce certain enzymes, including CYP3A4 (eg, phenytoin, barbiturates, carbamazepine) may decrease levels and potentially diminish effectiveness of therapy or increase breakthrough bleeding; use an alternative or back-up method of contraception and continue back-up contraception for 28 days after discontinuing the enzyme inducer. CYP3A4 inhibitors (eg, itraconazole, voriconazole, grapefruit juice) may increase levels. Significant changes in levels when coadministered w/ HIV protease inhibitors; decreased levels w/ nelfinavir, ritonavir, darunavir/ritonavir, (fos)amprenavir/ritonavir, lopinavir/ritonavir, and tipranavir/ritonavir, and increased levels w/ indinavir and atazanavir/ritonavir. Decreased levels w/ boceprevir, telaprevir, and nevirapine, and increased levels w/ etravirine. May decrease levels of acetaminophen (APAP), clofibric acid,

morphine, salicylic acid, and temazepam. May significantly decrease levels of lamotrigine and may reduce seizure control; dosage adjustment of lamotrigine may be needed. May need to increase dose of thyroid hormone in patients on thyroid hormone replacement therapy due to increased thyroid-binding globulin. **EE:** Colesevelam reported to significantly decrease EE exposure; decreased drug interaction reported when the 2 drug products are given 4 hrs apart. Atorvastatin or rosuvastatin may increase EE exposure; ascorbic acid and APAP may increase EE levels. May inhibit metabolism and increase levels of other compounds (eg, cyclosporine, prednisolone, theophylline, tizanidine, voriconazole).

PREGNANCY AND LACTATION

Pregnancy: Contraindicated in pregnancy.
Lactation: Not for use in nursing.

MECHANISM OF ACTION

Estrogen/progestogen oral contraceptive; acts by primarily suppressing ovulation. Also causes cervical mucus changes that inhibit sperm penetration and endometrial changes that reduce the likelihood of implantation. Acne: has not been established; increases sex hormone-binding globulin (SHBG) and decreases free testosterone.

PHARMACOKINETICS

Absorption: Rapid. Administration on various days of dosing cycle led to different parameters; refer to PI. **Distribution:** Found in breast milk. Norelgestromin and Norgestrel: Serum protein binding (>97%; norelgestromin bound to albumin; norgestrel bound primarily to SHBG). EE: Serum protein binding (>97% to albumin). **Metabolism:** Norgestimate: GI tract and/or liver (1st-pass). Norelgestromin (primary, active metabolite): Liver; norgestrel (active metabolite), hydroxylated and conjugated metabolites. EE: Hydroxylated metabolites and their glucuronide and sulfate conjugates. **Elimination:** Urine and feces (EE and norgestimate metabolites) (Norgestimate metabolites: 47% urine and 37% feces).

ASSESSMENT

Assess for DVT, PE, cerebrovascular disease, CAD, DM w/ vascular disease, headaches w/ focal neurological symptoms or migraine headaches w/ aura, pregnancy/nursing status, any other conditions where treatment is contraindicated or cautioned, and possible drug interactions.

MONITORING

Monitor for bleeding irregularities, venous/arterial thrombotic events, cervical cancer or intraepithelial neoplasia, retinal vein thrombosis or any other ophthalmic changes, jaundice, new/worsening headaches or migraines, depression, cholestasis w/ history of pregnancy-related cholestasis, pancreatitis, and other adverse reactions. Monitor BP in patients w/ HTN, glucose levels in diabetic or prediabetic patients, and lipid levels w/ dyslipidemia. Conduct a yearly visit in all patients for a BP check and for other indicated healthcare.

PATIENT COUNSELING

Inform of risk/benefits of therapy. Advise to take ud. Counsel that cigarette smoking increases the risk of serious CV events and women who are >35 yrs of age and smoke should not use combination oral contraceptives (COCs). Inform of the risk of VTE. Inform that the drug does not protect against HIV infection (AIDS) and other sexually transmitted infections. Advise not to use during pregnancy; if pregnancy occurs during use, instruct to stop further use. Instruct on what to do in the event tabs are missed. Counsel to use a back-up or alternative method of contraception when enzyme inducers are used w/ therapy. Inform that COCs may reduce breast milk production. Counsel women who start COCs postpartum and have not yet had a period, to use an additional method of contraception until an active pill has been taken for 7 consecutive days. Inform that amenorrhea may occur; consider pregnancy in the event of amenorrhea at the time of 1st missed period, and rule out pregnancy in the event of amenorrhea in 2 or more consecutive cycles.

STORAGE

20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F). Protect from light.

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