drosiprenone and estetrol
Nextstelis

Pharmaceutical company: Mayne Pharma

Pharmacologic classification: Estrogen-progestin combination
Therapeutic classification: Endocrine-metabolic agents

AVAILABLE FORMS
Tablets: 3 mg drospirenone and 14.2 mg estetrol as 24 active tablets, and 4 inert tablets per pack

INDICATIONS AND DOSAGES
To prevent pregnancy in females of reproductive potential
Women with no current use of hormonal contraception: One active tablet PO daily for 24 days beginning on day 1 of menstrual cycle. Then one inert tablet PO daily for 4 days. Begin each subsequent 28-day pack on the same day of the week as the first cycle pack; restart active tablets the next day after last inert tablet.

Women switching from another contraceptive method: One active tablet PO daily for 24 days beginning on the day when previous combined oral contraceptive would have started; or on the day when a new transdermal system, vaginal insert, or injection would have been scheduled; or on the day after removal of intrauterine system or implant; or on the day after the last progestin-only pill was taken. Then one inert tablet PO daily for 4 days. Begin each subsequent 28-day pack on the same day of the week as the first cycle pack; restart active tablets the next day after the last inert tablet.

Women starting after delivery of more than 20 weeks’ gestation or abortion or miscarriage after more than 14 weeks’ to 20 weeks’ or less gestation: Beginning no earlier than 4 weeks after delivery, follow directions for women with no current use of hormonal contraception if menses have resumed. If menses have not resume and the woman is not pregnant, use additional nonhormonal contraception for the first 7 days of use.

Women starting after abortion or miscarriage after 14 weeks’ or less gestation: Follow directions for women with no current use of hormonal contraception. If within the first 7 days after abortion or miscarriage, use additional nonhormonal contraception for the next 7 days.

CONTRAINDICATIONS AND CAUTIONS
- Contraindicated in females with a high risk of arterial or venous thrombotic diseases; evaluate patient for any past personal or family history of thrombotic or thromboembolic disorders and consider whether the history suggests an inherited or acquired hypercoagulopathy before starting medication. Risk factors for venous thromboembolism (VTE) (deep vein thrombosis, pulmonary embolism) include smoking, obesity, family history of VTE and prolonged immobilization.
- Contraindicated in females with current or history of a hormonally-sensitive malignancy (breast cancer), hepatic adenoma, hepatocellular carcinoma, acute hepatitis, or decompensated cirrhosis.
- Contraindicated in women with uterine bleeding of undiagnosed etiology.
- Contraindicated in females predisposed to hyperkalemia (renal impairment, hepatic impairment, adrenal insufficiency).
- Contraindicated in patients with uncontrolled hypertension (HTN) or HTN with vascular disease.
- Contraindicated in females who have migraines with aura; discontinue medication in females who develop new migraines that are recurrent, persistent, or severe, or who have an increase in frequency or severity of migraines with medication use.
- Avoid use in females with hereditary angioedema; medication may induce or exacerbate symptoms.
Avoid use in females with a history of chloasma gravidarum or increased sensitivity to sun or ultraviolet exposure.

- This drug may be less effective in females with a BMI of 30 kg/m² or greater.
- Safety and efficacy in females with a BMI 35 kg/m² or greater have not been established.
- Use of combined hormonal contraceptives may increase risk of CV events and is greatest in females over age 40, those with HTN, dyslipidemia, diabetes, or obesity, and those who use nicotine-containing products.
- Use cautiously in females with prediabetes or diabetes; medication may decrease glucose tolerance.
- Consider an alternate contraceptive method in females with personal or family history of hypertriglyceridemia; medication may increase triglyceride level and the risk for pancreatitis.
- Medication may increase the risk of developing or worsening existing gallbladder disease. Consider discontinuing use in females with symptomatic gallbladder or cholestatic disease.
- **Dialyzable drug:** Unknown.
- **Overdose S&S:** Nausea, vomiting, severe headache, thromboembolic complications, vaginal bleeding.

**PREGNANCY-LACTATION-REPRODUCTION**
- Discontinue hormonal contraceptives if pregnancy occurs.
- Hormonal contraceptives are present in human breast milk and may decrease milk production. Advise women who are breastfeeding to switch to an alternative form of birth control, if possible, taking into consideration the benefits of breastfeeding and the mother’s clinical need for contraception.

**INTERACTIONS**

**Drug-drug.** *Antibiotics:* May reduce contraceptive effectiveness. Advise use of backup contraception during coadministration.

*Antidiabetic drugs:* May reduce the blood glucose lowering effect of antidiabetic drugs. Increase frequency of glucose monitoring and increase antidiabetic drug dosage, as needed, based on glucose levels.

*Bile acid sequestrants* (*cholestyramine, colestipol, colesvelam*): May decrease absorption of contraceptive and lead to contraceptive failure or increase in breakthrough bleeding. Separate time of administration and refer to the sequestrants prescribing information for additional information.

*Drugs that may increase serum potassium level* (*ACE inhibitors, ARBs, NSAIDs, spironolactone, potassium supplements*): May increase serum potassium level. Monitor serum potassium level.

*Hepatitis C drug combinations containing ombitasvir-partaprevir-ritonavir, with or without dasabuvir:* May increase liver enzymes. Use together is contraindicated. May start drospirenone and estetrol 2 weeks after completion of hepatitis C combination drug regimen.

*Lamotrigine:* May decrease lamotrigine efficacy. Adjust lamotrigine dosage as recommended in prescribing information.

*Moderate and weak CYP3A4 inducers* (*dabrafenib, dexamethasone, modafinil, nafcillin*): May lead to contraceptive failure. Use an alternative or backup contraceptive method during coadministration and up to 28 days after discontinuation of the CYP3A inducer, unless the prescribing information of the inducer indicates no clinically significant interaction.

*Strong CYP3A inducers* (*phenytoin, phenobarbital, dexamethasone, rifampycin, rifampin*): May lead to contraceptive failure. Avoid concomitant use. If concomitant use is unavoidable, use an alternative contraceptive method or backup nonhormonal
contraceptive method during coadministration and up to 28 days after discontinuation of the inducer.

**Strong CYP3A inhibitors (ketoconazole, saquinavir, loperamide, diltiazem):** May increase risk of adverse drug reactions. Monitor serum potassium level in patients taking concomitantly long term.

**Systemic corticosteroids:** May increase the risk of corticosteroid-related adverse reactions. Monitor patient closely. Follow the recommendation for the corticosteroid in accordance with its prescribing information.

**Thyroid hormone replacement therapy:** May increase thyroid-binding globulin level. Monitor thyroid-stimulating hormone level and follow the recommendation for thyroid hormone replacement in accordance with its prescribing information.

**Drug-herb. St. John’s wort:** May reduce contraceptive effectiveness or increase breakthrough bleeding. Discourage use together or recommend alternative method of birth control.

**Drug-lifestyle. Black Box Warning: Smoking:** Cigarette smoking increases the risk of serious CV events from combined hormonal contraceptive use. Use together is contraindicated in females over age 35.

**Sun and ultraviolet light:** Drug may increase risk of chloasma. Limit exposure and wear sunscreen while taking this medication.

### ADVERSE REACTIONS

**CNS:** headache, mood disturbance.

**CV:** *thromboembolic disorders.*

**GU:** libido decrease, bleeding irregularities.

**Metabolic:** dysmenorrhea, weight increase.

**Skin:** acne.

**Other:** breast symptoms.

Reactions in bold italics are *life-threatening.*

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tivozanib
Fotivda

Pharmaceutical company: AVEO Pharmaceuticals

Pharmacologic classification: Kinase inhibitor
Therapeutic classification: Antineoplastic

AVAILABLE FORMS
Capsules: 0.89 mg, 1.34 mg

INDICATIONS AND DOSAGES
Treatment of relapsed or refractory advanced renal cell carcinoma following two or more prior systemic therapies
Adults: 1.34 mg PO once daily for 21 days followed by 7 days off treatment for a 28-day cycle. Continue treatment until disease progression or unacceptable toxicity.

Adjust-a-dose: If moderate hepatic impairment (total bilirubin greater than 1.5 to 3 times the upper limit of normal [ULN] with any AST), decrease dosage to 0.89 mg. Refer to the manufacturer’s instructions for toxicity-related dosage adjustments.

CONTRAINDICATIONS AND CAUTIONS
- This drug may cause severe hypertension and hypertensive crisis. Control blood pressure prior to initiating therapy and monitor the patient closely.
- This drug may cause serious or fatal cardiac failure, cardiac ischemia, arterial or venous thromboembolic events (MI, stroke), or hemorrhagic events. Closely monitor patients at risk for these events or those with a history of these events. Discontinue the drug if severe or life-threatening events occur.
- This drug may increase the risk of impaired wound healing; withhold therapy for at least 24 days before elective surgery and for at least 2 weeks following major surgery until adequate wound healing has occurred.
- This drug may cause reversible posterior leukoencephalopathy syndrome (RPLS). Evaluate patients with seizures, headaches, visual disturbances, confusion, or altered mental function with magnetic resonance imaging. Discontinue the drug in patients who develop RPLS.
- The 0.89-mg capsule contains FD&C Yellow No.5 (tartrazine), which may cause allergic-type reactions (including bronchial asthma) in susceptible patients.
- Safety and effectiveness have not been established in pediatric patients, or in patients with severe hepatic impairment (total bilirubin greater than 3 to 10 times ULN with any AST).
- **Dialyzable drug:** Unknown.
- **Overdose S&S:** Hypertension and hypertensive crisis.

PREGNANCY-LACTATION-REPRODUCTION
- Based on animal studies and mechanism of action, this drug can cause fetal harm. Advise women who are pregnant of the risk.
- Verify pregnancy status of females of reproductive potential prior to start of treatment.
- Females of reproductive potential and male patients with female partners of reproductive potential should use effective contraception during treatment and for one month after the last dose.
- There are no data on the presence of this drug in human milk, or the effects of this drug on the breastfed child, or on milk production. Because of the potential for serious adverse reactions in a breastfed child, advise a woman who is lactating not to breastfeed during treatment or for one month after the last dose.
- This drug can impair fertility in males and females of reproductive potential.
INTERACTIONS

ADVERSE REACTIONS
CNS: fatigue, delirium.
CV: bleeding, cardiac failure, cardiac ischemia, venous thromboembolism, arterial thromboembolism, hypertension.
EENT: dysphonia.
GI: diarrhea, nausea, stomatitis, vomiting, decreased appetite.
GU: acute kidney injury, proteinuria, increased creatinine.
Hematologic: decreased lymphocytes, decreased platelets, prolonged activated partial thromboplastin time, increased or decreased hemoglobin.
Hepatic: hepatobiliary disorders.
Metabolic: hypothyroidism, decreased weight.
Musculoskeletal: back pain, osteonecrosis.
Respiratory: pneumonia, respiratory failure, cough, dyspnea.
Skin: rash, palmar-plantar erythrodysesthesia syndrome.
Other: hypothyroidism.

Reactions in bold italics are life-threatening.

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viloxazine
Qelbree

Pharmaceutical company: Supernus Pharmaceuticals
Pharmacologic classification: Selective norepinephrine reuptake inhibitor
Therapeutic classification: ADHD drug

AVAILABLE FORMS
Capsules (extended-release): 100 mg, 150 mg, 200 mg

INDICATIONS AND DOSAGES
Treatment of attention-deficit hyperactivity disorder (ADHD)
Children ages 6 to 11 years: Initially, 100 mg PO once daily. May titrate by increments of 100 mg weekly to the maximum dose of 400 mg daily, depending on response and tolerability.
Children ages 12 to 17 years: Initially, 200 mg PO once daily. After one week, may titrate by increments of 200 mg to the maximum dose of 400 mg daily, depending on response and tolerability.

Adjust-a-dose: For severe renal impairment (eGFR less than 30 mL/min/1.73 m²), the recommended starting dose is 100 mg once daily. May titrate weekly by increments of 50 to 100 mg once daily, to a maximum dose of 200 mg once daily.

CONTRAINDICATIONS AND CAUTIONS
- **Black Box Warning:** Suicidal thoughts and behavior may increase when treated with this drug; monitor patients closely.
- This drug may induce manic or mixed episodes in patients with bipolar disorder. Screen patients prior to therapy for risk of bipolar disorder, including a detailed psychiatric history with personal and family history of suicide, bipolar disorder, and depression.
- Use cautiously in those with severe renal impairment.
- Use is not recommended in those with hepatic impairment.
- Safety and effectiveness have not been established in children younger than age 6.
- **Dialyzable drug:** Unknown.
- **Overdose S&S:** Drowsiness, impaired consciousness, diminished reflexes, and increased heart rate.

PREGNANCY-LACTATION-REPRODUCTION
- Based on animal studies, this drug may cause maternal and fetal harm when used during pregnancy. Discontinue when pregnancy is recognized, unless benefits to mother outweigh the risk.
- Health care providers are encouraged to register patients by calling the National Pregnancy Registry for Psychiatric Medications at 1-866-961-2388 or online at www.womensmentalhealth.org/preg.
- This drug may be present in breast milk. Consider the benefits of breastfeeding along with the mother’s need for the drug, and the risk to the child.

INTERACTIONS
**Drug-Drug.** CYP2D6 substrates (atomoxetine, desipramine, dextromethorphan, nortriptyline, metoprolol, nebivolol, perphenazine, tolterodine, venlafaxine, risperidone); CYP3A4 substrates (atipamezine, avanafil, buspirone, conivaptan, darifenacin, darunavir, ebastine, everolimus, ibrutinib, lomitapide, lovastatin, midazolam, naloregol, nisoldipine, saquinavir, simvastatin, sirolimus, tacrolimus, tipranavir, triazolam, vardenafil, lurasidone): May increase levels of these substrates and risk for adverse reactions. Monitor patient closely and adjust dose of the substrates...
as clinically indicated. 

Drugs that are moderately sensitive CYP1A2 substrates (clozapine, pirfenidone): May increase levels of sensitive substrates and risk for adverse reactions. Use together is not recommended. If coadministered, substrate dose reduction may be warranted.

Drugs that are sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range (alosetron, duloxetine, ramelteon, tasimelteon, tizanidine, theophylline): May increase levels of sensitive substrates and risk for adverse reactions. Use together is contraindicated.

MAO inhibitors: (selegiline, isocarboxazid, phenelzine, tranylcypromine, safinamide, rasagiline): May increase the risk of hypertensive crisis with concomitant treatment or within 14 days after discontinuing MAO inhibitor. Use during this timeframe is contraindicated.

ADVERSE REACTIONS
CNS: somnolence, fatigue, insomnia, lethargy, sedation, irritability, headache, pyrexia.
CV: increased diastolic blood pressure, tachycardia.
EENT: upper respiratory infection.
GI: decreased appetite, nausea, vomiting, abdominal discomfort or pain.

Reactions in bold italics are life-threatening.

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