

# NEW DRUG FAX SHEET



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This issue of *New Drug FAX Sheet* briefly reviews topics that include new drug approvals, new drug formulations, and new drug indications. If you need further information, please contact the Center for Healthcare Innovation and Patient Outcomes Research (CHIPOR) at [chipor@samford.edu](mailto:chipor@samford.edu).

## NEW DRUG APPROVALS

### **Epoetin Alfa-EPBX (Retacrit, Hospira)**

**Pharmacology:** Erythropoiesis-stimulating agent (ESA).

**Indication:** Treatment of anemia due to chronic kidney disease (CKD), zidovudine in patients with HIV-infection, effects of concomitant myelosuppressive chemotherapy, and reduction of allogenic RBC transfusions in patients undergoing elective, noncardiac, and nonvascular surgery.

**Adverse Drug Reactions:** Hypertension, arthralgia, muscle spasm, pyrexia, dizziness, medical device malfunction, vascular occlusion, and upper respiratory tract infection.

**Dose:** CKD-Initial dose 50-100 units/kg three times weekly; and 50 units/kg three times weekly for pediatric patients.

Dose of epoetin alfa-EPBX in patients receiving zidovudine: 100 units/kg three times weekly; patients on chemotherapy: 40,000 units/weekly or 150 units/kg three times weekly; surgery patients: 300 units/kg per day daily for 15 days or 600 units/kg weekly.

**Formulation:** Injection.

**Warnings/Contraindications:** Uncontrolled hypertension; pure red cell aplasia, and serious allergic reactions.

**Notes:** Increased mortality may be observed in Hgb levels > 11 g.dL.

### **Lofexidine hydrochloride (Lucemyra, US Worldmeds, LLC)**

**Pharmacology:** Central alpha-2-adrenergic agonist.

**Indication:** Mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.

**Adverse Drug Reactions:** Orthostatic hypotension, bradycardia, hypotension, dizziness, somnolence, sedation, and dry mouth.

**Dose:** 0.18 mg tablets orally four times daily at 5- to 6-hour intervals.

**Formulation:** Tablets, 0.18 mg.

**Warnings/Contraindications:** Risk of hypotension, bradycardia, and syncope; risk of QT prolongation.

**Notes:** Discontinue with gradual dose reduction over 2-4 days.

### **Erenumab-AOOE (Aimovig, Amgen)**

**Pharmacology:** Calcitonin gene-related peptide receptor antagonist.

**Indication:** Prevention of migraine in adults.

**Adverse Drug Reactions:** Injection site reactions and constipation.

**Dose:** 70 mg once monthly.

**Formulation:** Injection, 70 mg/mL.

**Warnings/Contraindications:** NA.

**Notes:** Administer subcutaneously in the abdomen, thigh or upper arm.

### **Sodium Zirconium Cyclosilicate (Lokelma, AstraZeneca)**

**Pharmacology:** Potassium binder.

**Indication:** Treatment of hyperkalemia.

**Adverse Drug Reactions:** Mild to moderate edema.

**Dose:** 10 g administered three times a day for up to 48 hours.

**Formulation:** 5 or 10 g per packet for oral suspension.

**Warnings/Contraindications:** Gastrointestinal adverse events in patients with motility disorders, and edema.

**Notes:** Dose can be adjusted at one-week intervals, as needed, to obtain the desired serum potassium target range.

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**Avatrombopag maleate (Doptelet, Akarx, Inc.)**

Pharmacology: Thrombopoietin receptor agonist.

Indication: Treatment of thrombocytopenia in adult patients with chronic liver disease.

Adverse Drug Reactions: Pyrexia, abdominal pain, nausea, headache, fatigue, and edema peripheral.

Dose: The dose is based on platelet count. If the platelet count is  $< 40 \times 10^9/L$ , the dose is 60 mg once daily for 5 days. If the platelet count is between  $40-49 \times 10^9/L$ , the dose is 40 mg once daily for 5 days.

Formulation: Tablet, 20 mg.

Warnings/Contraindications: Thrombotic/thromboembolic complications.

Notes: Avatrombopag maleate should be taken with food.

**Pegvaliase-PQPZ (Palynziq, Biomarin Pharm)**

Pharmacology: Phenylalanine-metabolizing enzyme.

Indication: Reduce blood phenylalanine concentrations in adult patients with phenylketonuria with uncontrolled blood phenylalanine concentrations greater than 600 micromol/L.

Adverse Drug Reactions: Injection site reactions, arthralgia, hypersensitivity reactions, headache, generalized skin reactions lasting at least 14 days, pruritus, nausea, abdominal pain, oropharyngeal pain, vomiting, cough, diarrhea, and fatigue.

Dose: Initial dosage is 2.5 mg subcutaneously once weekly for 4 weeks. The dose can be titrated over 5 weeks based on tolerability.

Formulation: Injection: 2.5 mg/0.5 mL, 10 mg/0.5 mL, and 20 mg/mL in a single-dose prefilled syringe.

Warnings/Contraindications: Hypersensitivity reactions.

Notes: Monitor for hypersensitivity reactions when used in combination with other PEGylated products, including anaphylaxis, with concomitant treatment.

**Baricitinib (Olmiant, Eli Lilly and Company)**

Pharmacology: Janus kinase (JAK) inhibitor.

Indication: Treatment of adult patients with moderately to severely active rheumatoid arthritis who had an inadequate response to one or more TNF antagonist therapies.

Adverse Drug Reactions: Upper respiratory tract infections, nausea, herpes simplex, and herpes zoster.

Dose: 2 mg once daily.

Formulation: 2-mg tablets.

Warnings/Contraindications: Serious infections, thrombosis, gastrointestinal perforations, live vaccinations.

Notes: Baricitinib should not be used in patients taking strong organic anion transporter 3 (OAT3) inhibitors.

## NEW DRUG FORMULATIONS

**Abiraterone acetate (Yonsa, Sun Pharma Global)**

Pharmacology: CYP17 inhibitor.

Indication: In combination with methylprednisolone for the treatment of patients with metastatic castration-resistant prostate cancer.

Dosage form: Tablets, 125 mg.

Dose: 500 mg administered once daily in combination with methylprednisolone 4 mg administered orally twice daily.

**Tacrolimus (Prograf, Astellas)**

Pharmacology: Calcineurin-inhibitor immunosuppressant.

Indication: Prophylaxis of organ rejection in patients receiving allogeneic liver, kidney or heart transplants.

Dosage form: Capsule, 0.5, 1, and 5 mg; injection 5 mg/mL; oral suspension: 0.2 mg.

Dose: Varies based on organ transplant.

**Halobetasol propionate (Halobetasol propionate, Theraps, Inc)**

Pharmacology: Corticosteroid.

Indication: Topical treatment of plaque psoriasis.

Dosage form: Topical foam.

Dose: Apply a thin film to the affected area twice daily for up to two weeks.

**Estradiol (Imvexxy, TherapeuticsMD, Inc)**

Pharmacology: Estrogen.

Indication: Treatment of moderate to severe dyspareunia.

Dosage form: Vaginal inserts containing 4 mcg or 10 mcg of estradiol.

Dose: One vaginal insert daily for 2 weeks, then insert 1 vaginal insert twice weekly.

**Amlodipin; Celecoxibl (Consensi, Kitov Pharmaceuticals, LTD)**

Pharmacology: Calcium channel blocker / celecoxib combination.

Indication: Treatment of hypertension and osteoporosis.

Dosage form: Tablets (amlodipine/celecoxib): 2.5 mg/200 mg, 5 mg/200 mg, or 10 mg/200 mg.

Dose: Start at (amlodipine/celecoxib) 5 mg/200 mg (2.5 mg/200 mg for small, elderly, or frail patients or hepatic impairment) orally once daily. Titrate to 5 mg/200 mg or 10 mg/200 mg once daily as needed for blood pressure control.

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