CENTER FOR HEALTHCARE INNOVATION AND PATIENT OUTCOMES RESEARCH

McWHORTER SCHOOL OF PHARMACY SAMFORD UNIVERSITY
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NEW DRUG FAX SHEET

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Volume 21 (Issue 3) **March 21, 2016**

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.

NEW DRUG APPROVALS

Brivaracetam (Briviact, UCB Inc.)

Pharmacology: Anticonvulsant; Synaptic vesicle protein 2A (SV2A) agonist.
Indication: Adjunctive therapy in the treatment of partial-onset seizures in patients ≥16 years with epilepsy.
Adverse Drug Reactions: somnolence/sedation, dizziness, fatigue and nausea/vomiting.
Dose: 50 mg twice daily. The dosage may be adjusted down to 25 mg twice daily or upward to 100 mg twice daily, based on tolerance.
Formulation: Tablets: 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg; oral solution: 10 mg/mL; and injection: 50 mg/5 mL single-dose vial.
Warnings/Contraindications: Suicidal behavior and ideation; neurological adverse effects (somnolence, fatigue), psychiatric adverse effects (psychotic symptoms, irritability, depression); hypersensitivity; and brivaracetam should be withdrawn gradually.
Notes: Significant drug-drug interactions occur with concomitant administration of brivaracetam with rifampin (increases in brivaracetam dose may be needed); carbamazepine (reduction in carbamazepine dose may be necessary; phenytoin (increases in phenytoin concentrations may occur); and no added benefit is observed when combined with levetiracetam.

Tofacitinib citrate (Xeljanz XR, Pfizer)

Pharmacology: anus kinase (JAK) inhibitor.
Indication: Treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate.
Adverse Drug Reactions: Upper respiratory tract infections, headache, diarrhea, and nasopharyngitis.
Dose: 11 mg once daily.
Formulation: Tablets: 11 mg.
Warnings/Contraindications: Avoid use during an active serious infection, gastrointestinal perforations, laboratory monitoring (monitor for changes in lymphocytes, neutrophils, hemoglobin, liver enzymes, and lipids); avoid use of live immunizations.
Notes: Prior to starting therapy, perform a test for latent tuberculosis. Lymphoma and other malignancies have been observed in patients treated with tofacitinib.

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NEW DRUG FORMULATIONS

Betamethasone diproionate (Sernivo, Promius Pharms, LLC.)
Pharmacology: Corticosteroid spray.
Indication: Treatment of mild to moderate plaque psoriasis.
Adverse Drug Reactions: Application site reactions (including pruritus, burning and/or stinging, pain, and atrophy).
Dose: Apply to affected skin areas twice daily.
Formulation: Spray 0.05% (equivalent to 0.5 mg betamethasone).
Warnings/Contraindications: May produce reversible HPA axis suppression; Cushing's syndrome, hyperglycemia, and unmasking of latent diabetes mellitus; pediatric patients may be more susceptible to systemic toxicity when treated with topical corticosteroids.

NEW DRUG INDICATIONS

Daclatasir (Daklinza, Bristol Myers Squibb)
Pharmacology: Hepatitis C virus NSSA inhibitor.
Indication: Used in combination with Sovaldi to treat patients with hepatitis C virus infection genotypes 1 and 3, HIV-1 co-infection, advanced cirrhosis and post-liver transplant recurrence of the infection.
Dose: 60 mg taken orally once daily with or without food.

Betamethasone diproionate (Harvoni, Gilead Science)
Pharmacology: Ledipasiv/sofosbuvir.
Indication: Treatment of adults with chronic hepatitis C virus infection with advanced liver disease. The indications allow for the treatment of liver transplant recipients with genotype 1 or 4 infection without cirrhosis or with compensated cirrhosis, and for genotype 1-infected patients with decompensated cirrhosis.
Dose: Ledipasivir 90 mg / sofosbuvir 400 mg taken orally once daily with or without food.

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New drug approvals, formulations, and indications. *New Drug Fax Sheet.* 2016 Mar 21;21(3):1-2.