

# 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

### **Acalabrutinib (Calquence, Acerta Pharma BV)**

**Pharmacology:** Kinase inhibitor.

**Indication:** Treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

**Adverse Drug Reactions:** anemia, thrombocytopenia, headache, neutropenia, diarrhea, fatigue, myalgia, and bruising.

**Dose:** The dose is 100 mg orally every 12 hours; the capsule should be swallowed whole with water (with or without food).

**Formulation:** 100-mg capsule.

**Warnings/Contraindications:** Hemorrhage and infection.

**Notes:** Avoid concomitant administration with strong CYP3A4 inhibitors and inducers. Dosing modifications may need to be made if these agents are administered together. Acalabrutinib should not be administered with proton pump inhibitors and the dosage of acalabrutinib should be staggered when H2 receptor antagonists and antacids are coadministered.

## NEW DRUG FORMULATIONS

### **Rolapitant (Varubi, Tesaro Inc.)**

**Pharmacology:** Substance P/neurokinin 1 (NK1) receptor antagonist.

**Indication:** Prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy.

**Dosage form:** 90-mg tablets; injectable emulsion: 166.5 mg/92.5 mL.

**Dose:** The recommended dosage of rolapitant tablets is 180 mg. The recommended dosage of the intravenous infusion is 166.5 mg over 30 minutes.

### **Exenatide Synthetic (Bydureon Bcise, AstraZeneca)**

**Pharmacology:** Glucagon-like peptide-1 (GLP-1) receptor agonist.

**Indication:** Improvement of glycemic control in adults with type 2 diabetes mellitus.

**Dosage form:** Extended-release suspension: 2 mg of exenatide in 0.85 mL single-dose autoinjector.

**Dose:** Administer 2 mg by subcutaneous injection once every seven days (weekly), without regard to meals.

### **Daptomycin (Daptomycin, Xellia Pharms APS)**

**Pharmacology:** Lipopeptide antibacterial.

**Indication:** Complicated skin and skin structure infection in adult patients and *S. aureus* bloodstream infections, including those with right-sided infective endocarditis in adult patients.

**Dosage form:** Lyophilized powder for reconstitution (350 mg).

**Dose:** Varies based on indication (4-6 mg/kg every 24-48 hours depending on kidney function).

### **Pregabalin (Lyrica CR, Pfizer)**

**Pharmacology:** Central nervous system agent.

**Indication:** Neuropathic pain associated with diabetic peripheral neuropathy (PN) and postherpetic neuralgia (PHN).

**Dose:** The initial dose is 165 mg day. Maximum dose is 550 mg/day for PHN.

**Triamcinolone acetonide (Zilretta, Flexion Therapeutics Inc.)**

Pharmacology: Extended-release synthetic corticosteroid.

Indication: Intra-articular injection for the management of osteoarthritis pain of the knee.

Dosage form: Injectable suspension that delivers 32 mg of triamcinolone acetonide.

Dose: The dose is 32 mg administered as a single intra-articular injection.

**Ascorbic acid (Ascor, McGuff Pharmaceuticals, Inc.)**

Pharmacology: Vitamin C.

Indication: Treatment of scurvy in adult and pediatric patients age 5 months and older for whom oral administration is not possible.

Dosage form: Injection-25,000 mg/50 mL (500 mg/mL)-Pharmacy bulk package.

Dose: Varies based on age. Pediatric patients should receive 50-100 mg once daily. Adults and pediatric patients > 11 years should receive 200 mg once daily.