



MaxorPlus Clinical Newsletter

July 2011

Now available

Xarelto® (rivaroxaban) is an oral anticoagulant that selectively and potently inhibits coagulation factor Xa. **Rivaroxaban** is indicated for the prophylaxis of deep vein thrombosis, which may lead to pulmonary embolism, in patients undergoing knee or hip replacement surgery. Unlike some other anticoagulants, the anticoagulant effect of **rivaroxaban** cannot be monitored with standard laboratory testing and is not easily reversed. Dosing is 10 mg PO daily for 12 days after knee replacement surgery or for 35 days after hip replacement surgery. Consider a dosage increase to 20 mg PO daily if coadministered with a combined P-glycoprotein and strong CYP3A4 inducer.
AWP \$ 8.10/ 10 mg tablet

Nulojix® (belatacept) IV is a selective T-cell costimulation blocker recently approved for prophylaxis of organ rejection in adult patients receiving a kidney transplant. **Nulojix®** is to be used in combination with **basiliximab** induction, **mycophenolate mofetil**, and **corticosteroids**. **Nulojix®** is indicated for use **only** in transplant patients who are Epstein-Barr virus (EBV) seropositive. Use in liver transplant patients is **not recommended** due to an increased risk of graft loss and death. Use of **Nulojix®** for the prophylaxis of organ rejection in other transplanted organs has not been established. Dosing is weight based and is on a specific schedule. Please refer to package insert for details. Maintenance dose is monthly and would be approximately 2 vials per dose.
AWP \$ 1107.60/ 250 mg vial or \$ 2215.20/ month

Based on **Nulojix's®** indication and cost, we recommend restricting to a specialty pharmacy.

Dificid® (fidaxomicin) is an oral macrolide antibiotic used to treat *Clostridium difficile*-associated diarrhea (CDAD). It is bactericidal against *C. difficile*, including hypervirulent strains. **Fidaxomicin** may have an increased sustained response as compared to oral vancomycin. Systemic absorption of **fidaxomicin** is **minimal**. Dosing is 200 mg PO twice daily for 10 days.
AWP \$ 168/ 200 mg tablet or \$ 3,360/ treatment course

Daliresp® (roflumilast) is the first in class phosphodiesterase-4 (PDE4) inhibitor. **Daliresp®** is indicated to reduce chronic obstructive pulmonary disease (COPD) exacerbations in patients with severe COPD associated with bronchitis and a history of exacerbations. **Roflumilast** undergoes extensive hepatic metabolism and use is contraindicated in patients with moderate to severe hepatic impairment. Dosing is 500 mcg PO daily. AWP \$ 6.90/tablet or \$207/ month

New generics available:

budesonide generic for **Entocort®** used for mild to moderate Crohn's disease

levofloxacin generic for **Levaquin®** antibiotic used to treat various infections

Zeosa generic for **Femcon FE®** chewable tablet used for birth control

triamcinolone nasal generic for **Nasacort AQ®** used for allergic rhinitis

Amethyst generic for **Lybrel®** used for birth control

Safety information

Erythropoiesis-Stimulating Agents (ESAs) In Chronic Kidney Disease: Drug Safety Communication

The FDA notified healthcare professionals that new, modified recommendations for more conservative dosing of **Erythropoiesis-Stimulating Agents (ESAs)** in patients with chronic kidney disease (CKD) have been approved to improve the safe use of these drugs. FDA has made these recommendations because of data showing increased risks of cardiovascular events with **ESAs** in this patient population. The new dosing recommendations are based on clinical trials showing that using **ESAs** to target a hemoglobin level of greater than 11 g/dL in patients with CKD provides no additional benefit than lower target levels, and increases the risk of experiencing serious adverse cardiovascular events, such as heart attack or stroke.

Healthcare professionals should weigh the possible benefits of using **ESAs** to decrease the need for red blood cell transfusions in CKD patients against the increased risks for serious cardiovascular events, and should inform their patients of the current understanding of potential risks and benefits. Therapy should be individualized to the patient and the lowest possible ESA dose given to reduce the need for transfusions.

ESAs include **Epogen®**, **Procrit®**, and **Aranesp®**.

FDA medwatch 6/24/11

The U.S. Food and Drug Administration (FDA) is notifying the public that the smoking cessation aid **Chantix®** ([varenicline](#)) may be associated with a small, increased risk of certain cardiovascular adverse events in patients who have cardiovascular disease. This safety information will be added to the Warnings and Precautions section of the **Chantix®** physician labeling.

Healthcare professionals should be aware that smoking is an independent and major risk factor for cardiovascular disease, and smoking cessation is of particular importance in this patient population. The known benefits of **Chantix®** should be weighed against its potential risks when deciding to use the drug in smokers with cardiovascular disease.

Patients are encouraged to read the Medication Guide they receive along with their Chantix prescription.

FDA medwatch 6/16/11

In Medical News

Restricted Access to Avandia®, Avandamet®, Avandaryl®

New restrictions have been added to the prescribing and use of medicines that contain [rosiglitazone](#). These medicines are used to treat type II diabetes. Patients will have to enroll in a special program to receive these drugs, and health care professionals cannot prescribe them without enrolling in the program.

[Rosiglitazone](#) may increase the risk of a heart attack and other heart and blood vessel (cardiovascular) problems. Because of these risks, FDA is restricting the use of [rosiglitazone](#) medicines to patients already being treated successfully with these medicines or in patients whose blood sugar cannot be controlled with other antidiabetic medicines and are unable to take [pioglitazone](#)-containing medicines (**Actos®**, **Actoplus Met®**, **Actoplus Met XR®**, or **Duetact®**). Be aware that after Nov. 18, 2011, patients will no longer be able to get their [rosiglitazone](#) medicine from a retail pharmacy. Patients must be enrolled in the **Avandia®-Rosiglitazone** Medicines Access Program to receive your medicine, which will only be available by mail order through certified pharmacies.