



MaxorPlus Clinical Newsletter

March 2011

Now available

Axiron® ([testosterone solution](#)) is indicated for hypogonadism (primary and hypogonadotropic types) or symptoms associated with andropause. Dose is 2 pump actuations (60 mg) daily. AWP \$ 334.32 per 90 gm bottle

Corifact® ([Factor XIII concentrate](#)) is indicated for prevention of bleeding in people with congenital factor XIII deficiency. Dosing is based on blood levels, given every 28 days. AWP \$ 9.36/ 1 unit

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

Benlysta® ([belimumab](#)) is indicated to treat patients with active autoantibody-positive lupus who are receiving standard therapy, including corticosteroids, antimalarials, immunosuppressives and non-steroidal anti-inflammatory medications. Given by IV infusion over 1 hour weekly for 3 weeks, then every 4 weeks thereafter. AWP \$ 531.82/ 120 mg dose and \$ 1772.71/ 400 mg dose

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

Edarbi® ([axilsartan medoxomil](#)) is a new ARB (angiotensin II receptor antagonist) approved for the treatment of hypertension either as monotherapy or in combination. Dosing is 40 to 80 mg daily. AWP \$ 2.94/ tablet 40 or 80mg

Makena® (hydroxyprogesterone caproate) is an IM injection indicated for preterm delivery prophylaxis in females with a singleton pregnancy who have a history of singleton spontaneous preterm birth. Dosing is 250 mg (1 mL) IM once weekly. Begin treatment anytime between 16 to 20 weeks of pregnancy until week 37. AWP \$ 1800.00/ 250 mg dose

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

New generics available:

jinteli generic for FemHRT® 1/5 used to treat menopausal symptoms
voriconazole generic for Vfend® used for treatment of fungal infections
latanaprost ophth generic for Xalatan® used to treat glaucoma

Safety Data

FDA Issues PPI-Magnesium Warning. FDA has issued a warning that prescription proton pump inhibitor (**PPI**) drugs may cause low serum magnesium levels (hypomagnesemia) if taken for prolonged periods of time (in most cases, longer than one year). Low serum magnesium levels can result in serious adverse events including muscle spasm (tetany), arrhythmias, and seizures; however, patients do not always have these symptoms.

Treatment of hypomagnesemia generally requires magnesium supplements. In approximately 25% of the cases reviewed, magnesium supplementation alone did not improve low serum magnesium levels and the **PPI** had to be discontinued. FDA does not specify whether OTC formulations of **PPIs** have been associated with hypomagnesemia, but the products are included on the list published by the agency.

Tshp website 3/7/11

FDA Announces Plans to Remove OTC Drugs From Market. FDA has announced that it intends to remove approximately **500** unapproved prescription **cough, cold, and allergy** drug products from the U.S. market. Unapproved drug products have not been evaluated by the FDA for safety, effectiveness, and quality. People may be at greater risk when using these products than when using FDA-approved prescription drugs or drugs that are appropriately marketed over-the-counter (OTC). The products subject to removal contain dextromethorphan, phenylephrine, guaifenesin, brompheniramine, chlorpheniramine, and other, similar drugs. There is a list of the unapproved prescription cough, cold, and allergy drug products the FDA intends to remove from the market and additional information the FDA website.

Tshp website 3/7/11