



## MaxorPlus Clinical Newsletter

June 2011

### Now available

**Phoslyra®** ([calcium acetate](#)) oral solution is for the treatment of hyperphosphatemia, especially in patients with chronic renal failure. Concentration of solution is 667 mg/5 ml.  
AWP \$ 96 for 473 ml bottle

**Incivek®** ([telaprevir](#)) is indicated to treat certain adults with chronic hepatitis C infection. Incivek is used for patients who have either not received interferon-based drug therapy for their infection or who have not responded adequately to prior therapies. Incivek is approved for use with interferon therapy made up of peginterferon alfa and ribavirin when initiated at the same time, not intended to be given in the middle of an existing Hepatitis C treatment program. Dosing is 750 mg three times a day for 12 weeks.  
AWP \$ 117.14/ 375 mg tablet or \$ 702.84/day or **\$ 59,038 for 12 week treatment**

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

**Victrelis®** ([boceprevir](#)) is indicated for treatment of chronic hepatitis C infection. Prior to initiating [boceprevir](#), patients must receive 4 weeks of treatment with [peginterferon alfa](#) and [ribavirin](#). Following the initial 4 weeks therapy, add [boceprevir](#) 800 mg (four 200 mg capsules) PO three times daily (every 7—9 hours). The duration of therapy is determined by the patient's HCV RNA concentrations at treatment weeks 4, 8, 12, and 24. If the patient has undetectable HCV RNA concentrations at weeks 8 and 24, discontinue all three medications at week 28. If HCV RNA is detectable at week 8 but undetectable at week 24, continue the three-drug regimen through week 36 and then administer only [peginterferon alfa](#) and [ribavirin](#) through treatment week 48.  
AWP \$ 15.71/ 200 mg capsule or \$ 188.52/day or **\$31,671 for 20 weeks**

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

**Edurant® (rilpivirine)** indicated for the treatment of antiretroviral treatment-naive adults with human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents. Dosing is 25 mg once daily with a meal.

AWP \$ 25.20/ tablet

**Viibryd® (vilazodone)** indicated for the treatment of major depression. Dosing is initially, 10 mg once daily for 7 days, then 20 mg once daily for 7 days. Thereafter the recommended dose is 40 mg once day. However, if patient is taking a potent CYP3A4 inhibitor concurrently, the maximum recommended dose is 20 mg once daily.

AWP \$ 4.74/ tablet for any strength

**New generics available:**

**carbamazepine capsules** generic for **Carbatrol®** used for seizures

**Neotic** generic for **Otozin®** otic drops used for the treatment of acute otic pain and inflammation

**bromfenac** generic for **Xibrom®** used for the treatment of postoperative ocular inflammation and ocular pain following cataract surgery

## **New OTC**

**fexofenadine** 180 mg generic for Allegra Allergy® used for allergic rhinitis.

## **Safety information**

Novo Nordisk reminded healthcare professionals of important safety information about **Victoza® (liraglutide)** injection required in a Risk Evaluation and Mitigation Strategy (REMS).

In clinical trials studying **Victoza®**, there were more cases of pancreatitis in patients treated with **Victoza®** than in patients treated with comparators.

FDA recommends after initiation of **Victoza®**, and after dose increases, observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back, and which may or may not be accompanied by vomiting).

FDA Medwatch 6/13/11

## Safety information

The U.S. Food and Drug Administration announced safety label changes for the cholesterol-lowering medication [simvastatin](#) because the highest approved dose-- 80 milligram (mg)--has been associated with an elevated risk of muscle injury or myopathy, particularly during the first 12 months of use.

The agency is recommending that [simvastatin](#) 80 mg be used only in patients who have been taking this dose for 12 months or more and have not experienced any muscle toxicity. It should not be prescribed to new patients. There are also new contraindications and dose limitations for when [simvastatin](#) is taken with certain other medications.

The changes to the label for [simvastatin](#)-containing medications are based on the FDA's review of the results of the seven-year Study of the Effectiveness of Additional Reductions in Cholesterol and Homocysteine clinical trial, other clinical trial data, and analyses of adverse events submitted to the FDA's Adverse Event Reporting System. All showed that patients taking [simvastatin](#) 80 mg daily had an increased risk of muscle injury compared to patients taking lower doses of [simvastatin](#) or other statin drugs. The risk of muscle injury is highest during the first year of treatment with the 80 mg dose of [simvastatin](#), is often the result of interactions with certain other medicines, and is frequently associated with a genetic predisposition for [simvastatin](#)-related muscle injury.

[Simvastatin](#) is sold under the brand-name **Zocor®** and as a single-ingredient generic product. It is also sold in combination with [ezetimibe](#) as **Vytorin®** and in combination with [niacin](#) as **Simcor®**.

FDA website announcement 6/8/11