



April 2009

Now available

Trilipix® (fenofibric acid) another oral antilipemic agent. AWP 45 mg \$1.44/tablet 135 mg \$ 4.31/tablet priced similar to other brand name fenofibrate products. Generic fenofibrate products are available.

Alvesco® (ciclesonide) is a glucocorticoid inhaler used for the treatment of asthma as prophylactic therapy in adults and adolescent patients 12 years of age and older. AWP for both 80 mcg and 160 mcg strengths \$ 186.62/inhaler.

Aplenzin® (bupropion HBr) a once daily treatment for depression. The molecular weight of the HBr salt is higher than the HCl salt, therefore a larger total mg dose of **Aplenzin®** is needed to provide the same amount of active drug when compared to the HCl forms of bupropion.

AWP 348 mg \$ 7.66/tablet and 522 mg \$17.44/tablet.

Generics of the HCl salt are available.

Vimpat® (lacosamide) is a functionalized amino acid used as an add-on therapy in the treatment of partial seizures in people with epilepsy who are 17 years or older. Due to the euphoria-type reactions similar to alprazolam it has been designated as a C-V. AWP ranges for doses 50-200 mg \$ 4.44-8.06/tablet with dosing usually twice daily.

Toviaz® (fesoterodine) is a muscarinic receptor antagonist used for the treatment of overactive bladder with symptoms of urinary incontinence, frequency or urgency. Dosing is 4 or 8 mg daily. AWP for both strengths is \$ 4.78/tablet.

Degarelix® (degarelix) a new injectable gonadotropin-releasing hormone (GnRH) receptor antagonist, indicated for patients with advanced prostate cancer.

Degarelix® provides fast, long-term suppression of testosterone, a hormone that stimulates prostate cancer growth. Degarelix is administered monthly by subcutaneous injection. The starting dose is 240 mg, followed by monthly maintenance doses of 80 mg. AWP 240 mg dose \$1,166.25 and 80 mg \$ 388.75.

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

Rapaflo® (silodosin) is an oral alpha-1 blocker used in the treatment of benign prostatic hyperplasia (BPH). Dosing is 8 mg daily. A 4 mg dose is available for patients with renal impairment. AWP 4 mg and 8 mg \$ 3.78/capsule.

Acanya gel® (clindamycin phos/benzoyl peroxide) is a combination product used in the treatment of acne vulgaris. AWP \$ 192.50/50 gm

Synvisc-One® (hylan G-F 20) a viscosupplementation product used to restore the cushioning and lubricating properties of normal joint fluid in the treatment of osteoarthritis of the knee in those who have failed to respond to more conservative therapy. It is a single injection version of **Synvisc®** which is administered as a series of 3 intra-articular injections.

Synvisc-One is 48mg/6 ml AWP \$ 880.00 and **Synvisc** AWP 293.34/injection

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

Vapisol® (conivaptan hydrochloride injection) is a therapy for the management of euvolemic and hypervolemic hyponatremia in hospitalized patients. VAPRISOL is not indicated for treatment of patients with congestive heart failure. It should only be used for the treatment of hyponatremia in patients with underlying heart failure when the expected clinical benefit of raising serum sodium outweighs the increased risk of adverse events for heart failure patients.

Dose is 20mg/100ml daily. AWP 596.22/100ml bag.

Temodar® (temozolomide) injection now available for treating malignant glioma and glioblastoma. AWP \$589.53/100 mg vial.

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

Afinitor® (everolimus) for the treatment of patients with advanced kidney cancer whose disease has progressed after treatment with other cancer therapies.

AWP 5 mg \$228.75/tablet or 10 mg \$241.45/tablet

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

Keppra XR® (levetiracetam) for the treatment of partial seizures. AWP 500 mg \$3.91/tablet or 750 mg \$ 5.88/tablet. The generic for regular release **Keppra®** is available in several strengths.

New generics available:

- **dextroamp-amphet ER** (generic for **Adderal XR®**) used for the treatment of attention-deficit hyperactive disorder.
- **risperidone odt** (generic for **Risperdal ODT®**) used for the treatment of schizophrenia or acute psychosis
- **topiramate** (generic drug for **Topamax®**) used for partial seizures

New indications

Eli Lilly & Co. has announced that the FDA has approved the bipolar depression drug **Symbyax**® ([fluoxetine/olanzapine](#)) as a therapy for treatment-resistant depression. The new indication applies to adult patients who have not responded to two separate rounds of therapy with different antidepressants.

Teva Pharmaceutical has announced that the FDA has approved the multiple sclerosis drug **Copaxone**® ([glatiramer](#)) as a preventative treatment for the condition. The drug is already approved to treat relapsing-remitting multiple sclerosis, where new symptoms occur suddenly or older symptoms become worse. The expanded approval allows for the drug's use in people who have experienced a first episode of multiple sclerosis and have magnetic resonance imaging results consistent with the condition.

Drug recalls

Caraco Pharmaceutical Laboratories announced that all tablets of Caraco brand [digoxin](#) 0.125 mg and [digoxin](#) 0.25 mg, distributed prior to March 31, 2009, which are not expired and are within the expiration date of September, 2011, are being voluntarily recalled to the consumer level. The tablets are being recalled because they may differ in size and therefore could have more or less of the active ingredient, digoxin. The recalled tablets were manufactured by Caraco Pharmaceutical Laboratories, Ltd.

Watson Pharmaceuticals Inc. is voluntarily recalling [propafenone](#) 100-count bottles of 225 milligram tablets because they may contain more of the active ingredient than specified. The affected group of tablets was shipped to customers between Oct. 15 and Nov. 26, 2008. No other strengths or shipments are included in the recall. Watson said that some patients can be very sensitive to small variations in doses, and may experience potentially serious side effects.

Safety warnings

New warning on the **Novantrone**[®] website: Prescreening of patients should include discussion of cardiac toxicity: Manufacturer suggests a patient's baseline left ventricular ejection fraction (LVEF) should be evaluated by echo contrast or a multiple gated acquisition (MUGA) scan and should be >50%. Patients should be questioned about symptoms of congestive heart failure prior to treatment. Regular evaluation of a patient's LVEF prior to each dose is imperative due to the risk of myocardial toxicity. If the LVEF decreases below 50%, therapy must be discontinued. In a clinical trial, LVEF decreased to <50% in 2 of 127 patients (2%) receiving Novantrone.

The FDA has ordered manufacturers of **metoclopramide** (brand name Reglan[®]) to add a **boxed warning** to drug labels about the risk of long-term or high-dose use. Chronic use of **metoclopramide** has been linked to tardive dyskinesia, which may include involuntary and repetitive movements of the body, even after the drug is no longer taken. These symptoms are rarely reversible and there is no known treatment. Manufacturers will be required to implement a risk evaluation and mitigation strategy [REMS] to ensure patients are provided with a medication guide that discusses this risk. Current product labeling warns of the risk of tardive dyskinesia with chronic metoclopramide treatment. For additional details, see the FDA MedWatch website.

FDA notified healthcare professionals and patients that certain **transdermal patches** (medicated patches applied to the skin), containing aluminum or other metals in the backing of the patches, can overheat during an MRI scan and cause skin burns in the immediate area of the patch. FDA is in the process of reviewing the labeling and composition of all medicated patches to ensure that those made with materials containing metal provide a warning about the risk of burns to patients who wear the patches during an MRI scan. Until this review is complete, FDA recommends that healthcare professionals referring patients to have an MRI scan identify those patients who are wearing a patch before the patients have the MRI scan. The healthcare professional should advise these patients about the procedures for removing and disposing of the patch before the MRI scan, and replacing the patch after the MRI scan. MRI facilities should follow published safe practice recommendations concerning patients who are wearing patches.

Read the MedWatch safety summary, including a link to the FDA Public Health Advisory, at: <http://www.fda.gov/medwatch/safety/2009/safety09.htm#Transdermal>

Drug Shortages

oxycodone immediate release tablets (5mg, 15mg and 30mg)

In the News

Committee Approves Granting FDA Authority over Tobacco.

The House Energy and Commerce Committee approved a bill on March 4 to allow FDA to regulate labeling, marketing, transport and the sale of [tobacco](#) products. The bill would not allow the agency to ban tobacco products entirely, but FDA could require the removal of harmful additives and even reduce the nicotine in cigarettes. The bill sponsored by Rep. Henry Waxman (D-CA) passed the House of Representatives last year but died in the Senate. Opponents raised concerns over the ability of FDA, which is struggling to meet its current regulatory obligations, to add another major category of product to regulate. The legislation has been a priority for several years for the American Lung Association, American Cancer Society and the American Heart Association.

Washington State to Allow Assisted Suicide.

A "Death with Dignity" law took effect in Washington State last week, allowing physicians to prescribe lethal medications to terminally ill patients with less than 6 months left to live. The bill was passed as a public initiative by nearly 60% of the vote in November. Media reports indicate that doctors are hesitant to talk publicly about how they will respond to the law. The law does not require physicians to write, or **pharmacists** to dispense, lethal prescriptions if they are opposed to the law. Some Washington hospitals have opted out of participation. Patients must be at least 18 years old, declared competent and must make 2 oral requests, 15 days apart. Two doctors must certify that the patient has a terminal condition and 6 months or less to live.

FDA Committee Recommends Withdrawal of [propoxyphene](#). By a 14-12 vote the FDA's Drug Safety and Risk Management and Anesthetic and Life Support Drugs advisory committees recently recommended that FDA withdraw [propoxyphene](#)-containing products from the U.S. market. The Agency has yet to take action on the recommendation, but traditionally has taken the advice of its advisory groups.

Tshp website 3/8/09