

New Drug Alerts

Pristiq™ (desvenlafaxine)

Relistor™ (methylnaltrexone)

Flector® (diclofenac)

Pristiq™ (desvenlafaxine)

Antidepressant

In February 2008, Wyeth Pharmaceuticals received approval from the U.S. Food and Drug Administration (FDA) to market **Pristiq™ (desvenlafaxine)**, the newest product to join Effexor XR® (venlafaxine) and Cymbalta® (duloxetine) in a special class of antidepressant agents. Similar to Effexor XR, Pristiq contains desvenlafaxine, the same active ingredient found in Effexor XR; however, Pristiq does not require metabolism (certain medications require activation) by the body to become active. Pristiq is currently FDA approved only for the treatment of depression in adult patients; although, it is currently being evaluated for the treatment of various painful conditions such as fibromyalgia and diabetic neuropathy in various clinical trials.

It is thought that Pristiq may play a significant role in replacing Effexor XR for the treatment of major depression in late 2008 when it is anticipated that Effexor XR will lose patent protection. Among injured workers, Effexor XR is used primarily for the treatment of a special type of pain called “neuropathic” or nerve pain; however, neither Pristiq nor Effexor are currently FDA approved for this indication. Recently, Effexor XR experienced a decline in market share in the workers’ compensation market due to aggressive marketing for Cymbalta (duloxetine), a similar antidepressant, which is FDA approved for the treatment of neuropathic pain. It is anticipated that Pristiq may replace some of Cymbalta’s market share in this sector. In 2007, Cymbalta accounted for 90% of all utilization increases within the antidepressant class and 7.7% of all prescription utilization increases. Due to a lack of pricing information for this agent, it is unknown what effects the release of Pristiq will have on spend in the workers’ compensation market.

Relistor™ (methylnaltrexone)

Laxative, Opioid-Induced Constipation

On April 24, 2008, **Relistor™ (methylnaltrexone)** received FDA approval for the treatment of constipation caused by the use of opioid pain relievers (i.e. morphine, oxycodone, etc.) in patients with advanced disease receiving palliative care when standard constipation therapy (i.e. stimulant laxatives, stool softeners, etc.) has been unsuccessful. Relistor was developed through a joint effort between Wyeth and Progenics Pharmaceuticals and is the first U.S. agent to target opioid-induced constipation in the palliative care population.

Relistor works by blocking opioids pain relievers in specific areas of the body; thereby, effectively reducing constipation without subsequently affecting the pain-relieving ability of opioid pain relievers. Relistor is currently only available in a subcutaneous injection dosage form and should not be administered more than once daily. Although various clinical trials have demonstrated Relistor’s safety and efficacy, its use beyond four months or in the pediatric population is yet to be determined. On average, laxative agents were ranked 34th in utilization and accounted for less than one percent (0.168 %) of total costs in 2007; however, it remains to be seen whether or not off-label use of this agent will drive an increase in laxative spend in the workers’ compensation market. As anticipated, Relistor became available in June 2008.

Flector® (diclofenac)

Topical Non-Steroidal Anti-Inflammatory Drug (NSAID)

Approved in early 2007 and recently becoming available in the U.S. market, Flector® (diclofenac) is the first available topical patch containing a non-steroidal anti-inflammatory drug (NSAID) in the United States. Much like other pain relievers in this class, such as ibuprofen and naproxen, Flector is thought to work by blocking the actions of various chemicals in the human body that are responsible for pain and inflammation.

Flector is currently FDA approved for the treatment of acute pain due to minor strains, sprains, and contusions and contains a black box warning regarding potential NSAID-related cardiovascular and gastrointestinal adverse side effects. Flector should not be used in patients with a history of ulcer disease or gastrointestinal bleeding. Patients should use the lowest effective dose for the shortest duration of treatment possible to help avoid these risks. Since its introduction into the U.S. market in early 2008, data indicates that Flector accounts for 4.9% of total NSAID expenditure and represents the 53rd drug in total drug expense. Data from 2008 indicates that 71% of injured workers are utilizing this agent an average of one prescription fill; however, the fill is on average 4.4 years after their industrial injury. This type of utilization pattern is inconsistent with Flector's FDA approved indication (i.e. acute care setting for minor painful injuries) and may possibly indicate that prescribers are utilizing the medication as add-on therapy to an injured worker's existing pain regimen.

TABLE 1: Comparison of Flector Costs to Other Common NSAIDs

Generic Name	Average Cost Per Prescription
Diclofenac Patch 1.3%	\$203.95
Celecoxib Capsule, 200 mg	\$155.73
Naproxen Tablet, 500 mg	\$37.26
Ibuprofen Tablet, 800 mg	\$15.12

Recent data suggests that the utilization of Flector may result in higher treatment costs than other available NSAID products, particularly if this agent is utilized outside of the acute injury setting. To put this into perspective, 13 injured workers could be treated with ibuprofen 800 mg for the same price as one Flector prescription (see Table 1). Based on this information, it is recommended that only a two-week supply (30 patches) be approved at a time with consideration being given to ensure utilization in the acute injury setting.

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Pristiq. Food and Drug Administration website. Available at www.accessdata.fda.gov <Accessed June 4, 2008>

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