



February 2011

**Now available**

**Abstral®** ([fentanyl transmucosal tablet](#)) to manage breakthrough pain for adults with cancer. [Fentanyl](#) immediate-release transmucosal medications are administered on the soft surfaces of the mouth (inside of the cheek, gums, tongue), or the nasal passages or throat where they dissolve and are absorbed. Available in doses ranging from 100 mcg to 800 mcg/tablet. AWP \$ 16.80/ 100 mcg tablet to \$ 48.00/ 800 mcg tablet

**Amturnide®** ([aliskiren/amlodipine/HCTZ](#)) this combination is not indicated for the initial treatment of hypertension, as the product contains fixed doses of 3 different antihypertensive drugs: [aliskiren](#) is a direct renin inhibitor; [amlodipine](#) is a dihydropyridine calcium-channel blocker; and [hydrochlorothiazide](#) (HCTZ) is a thiazide diuretic. The combination product may be substituted for the individually titrated components or as add-on/switch therapy in patients not achieving optimal blood pressure control. Available as 150-5-12.5 mg, 150-5-25 mg, 300-10-12.5, and 300-10-25 mg. AWP \$ 2.98-3.76/ tablet

**Prialt®** ([ziconotide acetate intrathecal](#)) is an intrathecally infused synthetic conopeptide derived from the venom of the piscivorous marine snail. [Ziconotide](#) is a calcium channel blocker specific to the neuronal calcium channels that regulate synaptic transmission in neurons. The non-opiate analgesic is effective for the treatment of severe, chronic pain due to various conditions, although the onset and amount of analgesia provided appear to be variable. [Ziconotide](#) is also being studied for spasticity associated with spinal cord trauma. Despite the advantage of offering patients a new non-opioid pain control option, the drug labeling carries a **Black Box Warning** regarding the potential for unacceptable side effects, such as severe psychiatric symptoms and neurological impairment that may lead to impaired cognition, hallucinations, and decreased consciousness. Dosing is by intrathecal infusion titrating to a maximum of 0.8 mcg/hour (19.2 mcg/day). AWP \$ 3834.70/ 500 mcg injection

Based on [Prialt's®](#) indication and cost, we recommend restricting to a specialty pharmacy.

**Natroba®** ([spinosad](#)) indicated for the treatment of pediculosis capitis (head lice infestation). AWP \$ 238.80/120 ml bottle.

**Fortesta®** ([testosterone gel](#)) indicated for the treatment of hypogonadism or symptoms associated with andropause. Dosing is 40 mg (4 pump actuations) applied once daily in the morning up to a maximum of 70 mg per day. AWP \$ 300.89/ 60 gm tube

**New generics available:**

[levofloxacin ophthalmic solution](#) generic for **Quixin®** indicated for the treatment of bacterial conjunctivitis

## In the news

### FDA Issues Warning on Asthma Drug in Preterm Labor

The FDA announced that [terbutaline](#) should not be used to prevent preterm labor or to treat it beyond 48 to 72 hours because of a potential for cardiac problems or death. The agency is requiring that a boxed warning and contraindications be added to the [terbutaline](#) label for both the injectable and tablet form of the drug. The warning applies to use both in the hospital and outpatient setting, the agency said.

[Terbutaline](#) is approved to prevent and treat bronchospasm associated with asthma, bronchitis and emphysema, but is sometimes used off-label for treating preterm labor and uterine hyperstimulation. [Terbutaline](#) also has been used off-label over longer periods of time in an attempt to prevent recurrent preterm labor, according to the FDA.

The agency said the label change was based on its review of postmarketing reports of maternal death and serious cardiovascular adverse events submitted to the Adverse Event Reporting System associated with obstetric use of [terbutaline](#).

### FDA extends Plavix® patent by 6 months to May 2012

The makers of **Plavix®**, said they will retain exclusive U.S. marketing rights to the blood thinner for an additional six months, under a decision by U.S. health regulators. The company announced that the Food and Drug Administration granted a six-month patent extension for **Plavix®** after the companies conducted extra studies of the drug in infants. With the extension, the company will be able to market the drug exclusively until May 17, 2012.

## Kentucky Proposes PSE Legislation.

The Kentucky legislature is considering a bill that would place [pseudoephedrine](#) (PSE) on prescription-only status, and similar legislation is being developed in Nevada, according to trade publications. Proponents of the legislation have used the significant reduction in [methamphetamine](#) busts in Oregon and Mississippi, where the law currently requires prescriptions for PSE purchases, in support of the bill.

TSHP website 1/24/11

The **Food and Drug Administration** is asking manufacturers of prescription combination products that contain [acetaminophen](#) to **limit the amount of acetaminophen to no more than 325 milligrams (mg) in each tablet or capsule.** The FDA also is requiring manufacturers to update labels of all prescription combination acetaminophen products to warn of the potential risk for severe liver injury.

[Acetaminophen](#), also called APAP, relieves pain and fever and can be found in both prescription and over-the-counter (OTC) products. It is combined in many prescription products with other ingredients, usually opioids such as [codeine](#) (**Tylenol with Codeine®**), [oxycodone](#) (**Percocet®**), and [hydrocodone](#) (**Vicodin®**). OTC acetaminophen products are not affected by today's action.

The elimination of higher-dose prescription combination acetaminophen products will be phased in over three years and should not create a shortage of pain medication. Patients and health care professionals are being notified of the new limitation on acetaminophen content, and of the labeling change, in a drug safety communication issued by CDER. The FDA believes that prescription combination products containing no more than 325 mg of acetaminophen per tablet are effective for treating pain.

[Acetaminophen](#) is also widely used as an over-the-counter pain and fever medication, and is combined with other OTC ingredients, such as cough and cold ingredients. The actions FDA is taking for prescription [acetaminophen](#) products do not affect OTC acetaminophen products.

## Safety Data

**Reminder: Use [dabigatran](#) within 30 days.**

**Pradaxa®** ([dabigatran](#)) must be **used within 30 days** after opening, according to information from the manufacturer (Boehringer Ingelheim). The lid of the bottle contains a desiccant to keep capsules of the drug stable, as humidity can quickly degrade the compound after the seal is removed. Patients receiving more than a month's supply would find the second month of therapy ineffective. Information on the limitation appears on the packaging, prescribing information and medication guide.

Tshp website 2/14/2011