

### Drugs recently approved or pending approval

#### LOPROX SHAMPOO

The US Food and Drug Administration (FDA) granted approval to Medicis Pharmaceutical Corp (Scottsdale, AZ) to market Loprox (ciclopirox) Shampoo 1% for the topical treatment of seborrheic dermatitis of the scalp in adults. The efficacy of Loprox Shampoo was evaluated in 2 randomized, double-blind clinical trials in patients age 16 years and older with seborrheic dermatitis of the scalp. Patients (N = 1071) applied Loprox Shampoo or its vehicle twice weekly for 4 weeks. The overall status of the seborrheic dermatitis and the presence and severity of erythema or inflammation and scaling were evaluated at week 4, using a scale on which 0 = none, 1 = slight, 2 = mild, 3 = moderate, 4 = pronounced, and 5 = severe. Effective treatment was defined as a score of 0 (or a score of 1 if the baseline score was 3) simultaneously for status of seborrheic dermatitis, erythema or inflammation, and scaling at week 4. Loprox Shampoo was shown statistically to be significantly more effective than the vehicle in both studies. Loprox Shampoo is not for ophthalmic, oral, or intravaginal use. In the clinical studies, the most frequent adverse effects reported were increased itching and other application site reactions (eg, burning, erythema) in 1% of patients. Approximately 1 teaspoon (5 mL) of Loprox Shampoo should be applied to wet hair and the scalp; the shampoo should be lathered and left on the hair and scalp for 3 minutes before rinsing. Treatment should be repeated twice weekly for 4 weeks, with a minimum of 3 days between applications.

#### OXYTROL

The FDA has approved marketing of Oxytrol (oxybutynin transdermal system) by Watson Pharmaceuticals, Inc, of Corona, CA, for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency. Clinical trials involving more than 1000 subjects at more than 50 US centers showed that Oxytrol provides effective control of OAB symptoms over a period of 3 to 4 days. In two phase III clinical trials, patients taking Oxytrol experienced up to a 75% decrease in urinary incontinence episodes (study 1 = 61% reduction; study 2 = 75% reduction), compared with a 50% reduction in both placebo groups. In study 1, 15% of patients taking Oxytrol achieved complete continence, compared with 8.6% of patients taking placebo; in study 2, 39% of patients in the Oxytrol group achieved complete continence, compared with 22% of patients in the placebo group. The

most common adverse effects of Oxytrol were application site reactions. Oxytrol should be used with caution in patients with ulcerative colitis, intestinal atony, myasthenia gravis, or gastroesophageal reflux or in patients who are taking drugs (eg, bisphosphonates) that can cause or exacerbate esophagitis. Oxytrol is contraindicated in patients with urinary retention, gastric retention, or uncontrolled narrow-angle glaucoma and in patients who are hypersensitive to oxybutynin or other components of Oxytrol. Oxytrol is a thin, flexible, clear patch that should be applied to the abdomen, hip, or buttock twice weekly.

#### RELPAK

Pfizer, Inc, of New York, NY, received approval from the FDA to market Relpax (eletriptan hydrobromide) for the acute treatment of migraine with or without aura in adults. The effi-

cacy of Relpax was evaluated in 8 randomized, double-blind, placebo-controlled studies involving more than 9000 patients. In all studies, patients were instructed to treat a moderate to severe headache. Headache response, defined as a reduction in headache severity from moderate or severe pain to mild or no pain, was assessed up to 2 hours after dosing with either Relpax 40 mg or placebo.

Associated symptoms (eg, nausea, vomiting, photophobia, phonophobia) were also assessed. Maintenance of response was assessed for up to 24 hours after dosing. In the 7 adult studies, the percentage of patients achieving headache response 2 hours after treatment was significantly greater among patients receiving Relpax 40 mg compared with those receiving placebo (range, 22.8%–42.6% over placebo). The most common adverse effects were asthenia, nausea, dizziness, and somnolence. Relpax is contraindicated in patients with ischemic heart disease or other significant cardiovascular diseases, cerebrovascular syndromes, peripheral vascular disease, uncontrolled hypertension, or hemiplegic or basilar migraine. The maximum recommended single dose of Relpax is 40 mg. If, after the initial dose, the headache improves but then returns, a repeat dose may be beneficial and can be taken at least 2 hours after the initial dose. The maximum daily dose should not exceed 80 mg.



Compiled from press reports and pharmaceutical company press releases. For more information, contact Jennifer M. Lehr, Hospital Physician, 125 Stafford Avenue, Suite 220, Wayne, PA 19087-3391.

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