

Drugs recently approved or pending approval

COMBUNOX

The US Food and Drug Administration (FDA) has granted approval to Forest Laboratories, Inc. (St. Louis, MO) to market Combunox (oxycodone HCl and ibuprofen) for the short-term (no more than 7 days) management of acute, moderate-to-severe pain. Combunox is the only fixed-dose combination of oxycodone HCl (5 mg) and the nonsteroidal anti-inflammatory drug ibuprofen (400 mg) to be approved by the FDA. Combunox was evaluated in 3 double-blind, placebo-controlled studies: 2 studies involved patients following dental surgery (N = 949), and study 3 involved patients following abdominal/pelvic surgery (N = 456). In all 3 studies, patients were given a single dose of Combunox, ibuprofen alone, oxycodone HCl alone, or placebo for acute, moderate-to-severe pain. Combunox produced greater efficacy than placebo and in each of Combunox's individual components in all 3 studies as measured by the magnitude of pain relief and the reduction in pain intensity through 6 hours. The most common adverse effects observed with Combunox were nausea, vomiting, somnolence, and dizziness. Dosage should not exceed 4 tablets in a 24-hour period and should be given for no more than 7 days.

TYSABRI

The FDA has given approval to Biogen Idec Inc. (Cambridge, MA) to market Tysabri (natalizumab) for the treatment of patients with relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations. Tysabri was evaluated in 2 ongoing randomized, double-blind, placebo-controlled trials. Patients were enrolled in the studies if they experienced at least 1 clinical relapse during the prior year and had a Kurtzke Expanded Disability Status Scale score between 0 and 5. In both studies, neurologic examinations were performed every 12 weeks and at times of suspected relapse. Magnetic resonance imaging for T1-weighted gadolinium-enhancing lesions and T2-hyperintense lesions were performed annually. In study 1, patients who had not received any interferon- β or glatiramer acetate were randomized to receive Tysabri 300 mg intravenous infusion (n = 627) or placebo (n = 315) every 4 weeks for up to 28 months. In study 2, patients who had experienced 1 or more relapses while on treatment with Avonex (interferon beta-1a) 30 μ g intramuscularly once weekly during the previous year were randomized to receive Tysabri 300 mg (n = 589) or placebo (n = 582) every 4 weeks for up to 28 months. All patients continued to receive Avonex 30 μ g once weekly. 76% of Tysabri-treated patients in study 1 remained relapse-free as compared with

53% for placebo-treated patients. In study 2, 67% of Tysabri-treated patients remained relapse-free as compared with 46% of placebo-treated patients. The most common adverse effects observed with Tysabri administration were headache, fatigue, urinary tract infection, depression, lower respiratory infection, and arthralgia. Tysabri should be administered at a dose of 300 mg intravenously every 4 weeks.

VESICARE

Yamanouchi Pharma America, Inc. (Paramus, NJ) and Glaxo-SmithKline (Research Triangle Park, NC) have been given approval by the FDA to market VESicare (solifenacin succinate) for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency. VESicare was evaluated in four 12-week, double-blind, randomized, placebo-controlled, parallel group, multicenter trials involving 3027 patients (n = 1811 for VESicare; n = 1216 for placebo). Two of the 4 studies evaluated the 5- and 10-mg

VESicare doses, and the other 2 studies evaluated the 10-mg dose only. The primary endpoint in all 4 trials was the mean change from baseline to 12 weeks in number of micturitions/24 h. Secondary endpoints were mean change from baseline to 12 weeks in number of incontinence episodes/24 h and mean volume voided per micturition. The mean reduction in the number of micturitions/

24 h was significantly greater with VESicare 5 and 10 mg compared with placebo (2.3 and 2.7 versus 1.4, respectively). The mean reduction in the number of incontinence episodes/24 h was significantly greater with VESicare 5 and 10 mg as compared with placebo (1.5 and 1.8 versus 1.1, respectively). The mean increase in the volume voided per micturition was also significantly greater with VESicare 5 and 10 mg compared with placebo (32.3 mL and 42.5 mL versus 8.5 mL, respectively). The most common adverse effects observed with VESicare were dry mouth, constipation, and blurred vision. VESicare is contraindicated in patients with urinary retention, gastric retention, and uncontrolled narrow-angle glaucoma. The recommended dose of VESicare is 5 mg once daily. The dose may be increased to 10 mg once daily if the 5-mg dose is well tolerated.



Compiled from press reports and pharmaceutical company press releases. For more information, contact Tricia Faggioli, Hospital Physician, 125 Strafford Avenue, Suite 220, Wayne, PA 19087-3391.