

Drugs recently approved or pending approval

CANCIDAS

Merck & Co., Inc (Whitehouse Station, NJ) received approval to market Cancidas (caspofungin acetate) for the treatment of invasive aspergillosis in patients who are refractory to or intolerant of other therapies (ie, amphotericin B, lipid formulations of amphotericin B, and/or itraconazole). An open-label, non-comparative study evaluated the safety, tolerability, and efficacy of Cancidas in 69 patients between 18 and 80 years of age with invasive aspergillosis who had previously been refractory to or intolerant of other antifungal therapies. Patients were administered a single intravenous (IV) 70-mg loading dose of Cancidas and subsequent daily IV doses of 50 mg. The mean duration of therapy was 33.7 days, with a range of 1 to 162 days. A favorable response to therapy was defined as either complete resolution or clinically meaningful improvement of all signs and symptoms and attributable radiographic findings. Overall, 41% (26/63) of patients receiving at least 1 dose of Cancidas responded favorably to treatment. For those patients who received more than 7 days of therapy, 50% (26/52) had a favorable response. The favorable response rates for patients who were either refractory to or intolerant of previous therapies were 36% (19/53) and 70% (7/10), respectively. Concomitant use of Cancidas with cyclosporine is not recommended unless the potential benefit outweighs the potential risk to the patient. Common adverse effects associated with Cancidas include fever, phlebitis, infused vein complications, nausea, and headache. The recommended dosage of Cancidas is a single 70-mg IV loading dose administered on day 1, followed by a 50-mg IV dose once daily thereafter.



GEODON

The United States Food and Drug Administration approved marketing of Geodon (ziprasidone HCl) capsules by Pfizer, Inc (New York, NY) for the treatment of schizophrenia. The efficacy of Geodon was evaluated in 5 placebo-controlled studies—4 short-term (4- and 6-week) trials and 1 long-term (52-week) trial. In the short-term trials, dosages of Geodon ranging from 20 to 100 mg twice daily were statistically superior to placebo for treatment of positive and negative symptoms in patients with acute exacerbation of schizophrenia and schizoaffective disorder. In the 52-week, placebo-controlled trial, symptomatically stable schizophrenic inpatients (N = 294) were randomized to 3 fixed doses of Geodon (20, 40, or 80 mg twice daily) or placebo. Patients were observed for “impending psychotic relapse,” defined as a Clinical Global Impression improvement score of

≥ 6 and/or scores ≥ 6 on the hostility or uncooperativeness items of the Positive and Negative Syndrome Scale on 2 consecutive days. Geodon was significantly superior to placebo in time to relapse and in rate of relapse, with no significant difference between the different dosage groups. Geodon is contraindicated in patients with a known history of QT prolongation, with recent acute myocardial infarction, or with uncompensated heart failure. Common adverse events associated with Geodon include nausea, dizziness, somnolence, constipation, and abnormal muscle movements. Geodon capsules should be administered at an initial dose of 20 mg twice daily with food. In some patients, daily dosage may be adjusted up to 80 mg twice daily, based on individual clinical status.

NEXIUM

Approval was granted to AstraZeneca LP (Wilmington, DE) to market Nexium (esomeprazole magnesium) delayed-release capsules for treatment of heartburn and other symptoms associated with gastroesophageal reflux disease (GERD) and for the short-term treatment in healing of erosive esophagitis (EE). Nexium is also indicated for the maintenance of healing of erosive esophagitis and, in combination with amoxicillin and clarithromycin, for eradication of *Helicobacter pylori* infection in patients with duodenal ulcer disease. Four multicenter, double-blind, randomized studies evaluated the healing rates of Nexium 20 mg and Nexium 40 mg against AstraZeneca's Prilosec (omeprazole) 20 mg in patients with diagnosed EE. Trial results showed that Nexium 20 mg and 40 mg provided excellent healing rates (89.9% to 94.1%) and resolution of heartburn symptoms in patients with EE. The most common adverse events associated with Nexium include headache, diarrhea, nausea, flatulence, abdominal pain, constipation, and dry mouth. The dosing regimens for Nexium are as follows: 20 mg or 40 mg once daily for 4 to 8 weeks for healing of EE; 20 mg once daily for the maintenance of healing of EE; 20 mg once daily for 4 weeks for heartburn and other symptoms associated with GERD; and 40 mg once daily for 10 days, in combination with clarithromycin 500 mg twice daily for 10 days and amoxicillin 1000 mg twice daily for 10 days, for the eradication of *H. pylori* infection.

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

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