Drugs recently approved or pending approval

CLARINEX SYRUP

The US Food and Drug Administration (FDA) has given approval to Schering-Plough Corp. (Kenilworth, NJ) to market Clarinex (desloratadine) Syrup for the relief of nasal and nonnasal symptoms of seasonal allergic rhinitis (AR) in patients aged > 2 years, for relief of symptoms of perennial AR in patients aged > 6 months, and for symptomatic relief of pruritis and reduction in number and size of hives in patients with chronic idiopathic urticaria (CIU) aged > 6 months. With the CIU and perennial AR indications, Clarinex Syrup is the only prescription nonsedating antihistamine for a patient population as young as 6 months. Clarinex Syrup was evaluated in 3 double-blind, placebo-controlled, 15-day safety studies involving pediatric patients with a history of AR, CIU, or those who were candidates for antihistamine therapy. In study 1, Clarinex Syrup 2.5 mg was given to patients aged 6 to 11 years (n = 60). In study 2, Clarinex Syrup 1.25 mg was given to patients aged 2 to 5 years (n = 55). In study 3, Clarinex Syrup 1.25 mg was administered to patients aged 12 to 23 months (n = 65), and a 1.0-mg dose was given to patients aged 6 to 11 months (n = 66). Study results demonstrated safety for the use of Clarinex Syrup in patients aged 6 months to 11 years. The most common adverse effects associated with Clarinex Syrup were upper respiratory infection, diarrhea, fever, urinary tract infection, irritability, and cough.

GEODON

The FDA has given Pfizer Inc. (New York, NY) approval to market Geodon (ziprasidone HCl) for the treatment of acute mania or mixed episodes associated with bipolar disorder, with or without psychotic features. The efficacy of Geodon was evaluated in 2 placebo-controlled, double-blind, 3-week studies. The Mania Rating Scale (MRS) and the Clinical Global Impression–Severity of Illness Scale (CGI-S) were used to measure manic symptoms. In study 1, Geodon-treated patients (n = 210) were given 40 mg twice daily on day 1 and 80 mg twice daily on day 2. Titration within 40 to 80 mg (in 20-mg twice-daily increments) was permitted for the duration of the study. In study 2, Geodon-treated patients (n = 205) were given 40 mg twice daily on day 1. Titration within 40 to 80 mg twice daily (in 20-mg twice-daily increments) was permitted for the duration of the study beginning on day 2. In both studies, Geodon was significantly more effective than placebo in reduction of the MRS total score and the CGI-S score. The most common adverse effects observed with Geodon were somnolence, dizziness, and extrapyramidal symptoms. The recommended initial daily dose of Geodon is 40 mg twice daily with food. The dose should then be increased to 60 mg or 80 mg twice daily on the second day of treatment and subsequently adjusted based on tolerance and efficacy. Geodon is also approved for the treatment of schizophrenia.

PALLADONE

Purdue Pharma L.P. (Stamford, CT) has been given FDA approval to market Palladone (hydromorphone HCl extended-release) for the management of persistent, moderate-to-severe pain in patients requiring continuous, around-the-clock analgesia for an extended period of time. The efficacy of Palladone was evaluated in a double-blind, randomized, parallel group, multicenter, placebo-controlled, 4-week trial of patients with pain that was present for at least 1 month. Patients (N = 121) were randomized to either 12-mg Palladone or placebo after they had demonstrated that they needed approximately 12 mg immediate-release hydromorphone around-the-clock to improve pain control. Palladone-treated patients maintained adequate analgesia for a significantly longer period of time than placebo-treated patients. The most common adverse effects seen with Palladone use were constipation and nausea. Administering broken, chewed, crushed, opened, or dissolved Palladone capsules can lead to rapid release and absorption of a potentially fatal dose of hydromorphone. Physicians should individualize dosing regimens for each patient, taking into account the patient's prior opioid treatment. Overestimating the Palladone dose when converting patients from another opioid medication can result in a fatal overdose with the first dose. Dosage adjustment can be carried out as frequently as every 2 days when clinically necessary. If more than 2 doses of rescue medication are needed within a 24-hour period for 2 consecutive days, the Palladone dose should usually be titrated upward. When the patient no longer requires therapy, Palladone doses should be tapered gradually to prevent signs and symptoms of withdrawal.

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.*