

Drugs recently approved or pending approval

ARANESP

Amgen Inc (Thousand Oaks, CA) received approval to market Aranesp (darbepoetin alfa) for the treatment of anemia associated with chronic renal failure (CRF), including patients on dialysis and patients not on dialysis. The safety and efficacy of Aranesp was evaluated in 12 clinical trials involving more than 1500 adult patients with CRF. One trial, a 24-week pivotal study, involved 166 erythropoietin-naïve patients with CRF. Patients had baseline hemoglobin (Hb) values less than 11.0 g/dL and were randomized to receive either 0.45 µg/kg body weight of Aranesp once weekly (n = 129) or 50 U/kg of epoetin alfa twice weekly (n = 37). When necessary, dosage adjustments were made to maintain Hb within the study target range of 11.0 to 13.0 g/dL. Results showed that 93% (95% CI: 87%, 97%) of patients treated with Aranesp and 92% (95% CI: 78%, 98%) of patients treated with epoetin alfa achieved the primary efficacy endpoint of an increase in Hb of at least 1.0 g/dL from baseline to a value of at least 11.0 g/dL. Aranesp is contraindicated in patients with uncontrolled hypertension and may increase the risk of cardiovascular events, including death, in patients with CRF. The most commonly reported adverse events associated with Aranesp are infection, hypertension, hypotension, myalgia, headache, and diarrhea. The recommended starting dosage of Aranesp is 0.45 µg/kg administered either intravenously or subcutaneously once weekly. Doses should be titrated not to exceed a target Hb concentration of 12 g/dL.



ENTOCORT EC

The US Food and Drug Administration has approved marketing of Entocort EC (budesonide) capsules by AstraZeneca LP (Wilmington, DE) for the treatment of mild to moderate active Crohn's disease involving the ileum and/or the ascending colon. The safety and efficacy of Entocort EC were evaluated in 5 randomized and double-blind clinical trials involving 994 patients with this type of Crohn's disease. Clinical improvement was defined as achievement of a score of less than or equal to 150 on the Crohn's Disease Activity Index (CDAI). One study compared the safety and efficacy of Entocort EC 9 mg once daily in the morning to a comparator. At baseline, the median CDAI score was 272. After 8 weeks of treatment, 69% of patients in the Entocort EC 9 mg group and 45% of patients in the comparator group experienced clinical improvement. The most common adverse events associated with Entocort EC are headache,

respiratory infection, nausea, and symptoms of hypercorticism. Entocort EC should be used in pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus. The recommended adult dosage of Entocort EC for the treatment of mild to moderate active Crohn's disease involving the ileum and/or the ascending colon is 9 mg (three 3-mg capsules) taken once daily in the morning for up to 8 weeks.

SPECTRACEF

Approval was granted to TAP Pharmaceutical Products Inc (Lake Forest, IL) to market Spectracef (cefditoren pivoxil) tablets for the treatment of the following mild to moderate infections in adults and adolescents (12 years of age or older): acute bacterial exacerbation of chronic bronchitis (AECB), pharyngitis/tonsillitis, and uncomplicated skin and skin structure infections. Spectracef may be used to treat AECB caused by *Haemophilus influenzae*, *H. parainfluenzae*, *Streptococcus pneumoniae* (only strains susceptible to penicillin), or *Moraxella catarrhalis*; pharyngitis/tonsillitis caused by *Streptococcus pyogenes*; and uncomplicated skin and skin structure infections caused by *Staphylococcus aureus* or *Streptococcus pyogenes*. The safety and efficacy of Spectracef were evaluated in clinical trials involving 4299 adult and adolescent subjects. The drug performed well, with most adverse events being mild and self-limiting. The most common adverse events associated with the use of Spectracef include diarrhea, nausea, and vaginal moniliasis. Spectracef is contraindicated in patients with known allergy to the cephalosporin class of antibiotics or any of its components and in patients with carnitine deficiency or inborn errors of metabolism that may result in clinically significant carnitine deficiency. Patients with milk protein (sodium caseinate) hypersensitivity (not lactose intolerance) should not receive Spectracef, and the drug should not be taken concomitantly with antacids or H₂ receptor antagonists. The recommended dosage of Spectracef for the treatment of AECB is 400 mg twice daily with meals for 10 days, and the recommended dosage for the treatment of pharyngitis/tonsillitis and uncomplicated skin and skin structure infections is 200 mg twice daily with meals for 10 days.

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.