Drugs recently approved or pending approval

ADVICOR

The US Food and Drug Administration (FDA) has approved marketing of Advicor (niacin extended release and lovastatin tablets) by Kos Pharmaceuticals, Inc (Miami, FL) for the treatment of primary hypercholesterolemia and mixed dyslipidemia in patients previously treated with either component who require additional lipid modification for low-density lipoprotein (LDL) or high-density lipoprotein cholesterol and triglycerides beyond that achieved by the individual components. In a multicenter, randomized, double-blind, parallel, 28-week, active-comparator study in patients with type IIa and IIb hyperlipidemia, Advicor was compared to each of its components (niacin and lovastatin). Patients received each dose for at least 4 weeks in a forced dose-escalation study design. Results for LDL mean percentage change from baseline (the primary efficacy variable) showed that LDL-lowering with Advicor was significantly greater than that achieved with lovastatin 40 mg only after 28 weeks of titration to a dose of 2000 mg (niacin)/40 mg (lovastatin) ($P < .0001$) and that Advicor at doses of 1000 mg/20 mg or higher achieved greater LDL-lowering than did niacin alone ($P < .0001$). Advicor is contraindicated in patients with known hypersensitivity to niacin or lovastatin (or any component of this medication), active liver disease or unexplained persistent elevations in serum transaminase levels, active peptic ulcer disease, and arterial bleeding. Pregnant or nursing women also should not use Advicor. The most frequently reported adverse events include flushing, upset stomach, and rash. Advicor tablets are available in 3 different strengths of extended-release niacin (500, 750, and 1000 mg), each combined with 20 mg of lovastatin. The maximum recommended total dose of Advicor is 2000 mg/40 mg (ie, two 1000 mg/20 mg tablets). Advicor tablets should be swallowed whole at bedtime with a low-fat snack.

ARIXTRA

Akzo Nobel's (Arnhem, Netherlands) business unit Organon (West Orange, NJ) and Sanofi-Synthelabo (Paris, France) received approval from the FDA to market Arixtra (fondaparinux sodium) injection for the prophylaxis of deep vein thrombosis in patients undergoing surgery for hip fracture repair, hip replacement, and knee replacement. A synthetic compound, Arixtra is the first in a new class of antithrombotic agents that selectively inhibit Factor Xa. Efficacy of Arixtra was evaluated in randomized double-blind clinical trials conducted in 8000 patients, more than 4000 of whom received Arixtra for hip fracture, hip replacement, or knee replacement surgeries. Those given Arixtra were 50% less likely to develop a clot than those given enoxaparin sodium. The patient population included men and women ranging in age from 17 to 97 years and in body weight from 66 to 373 pounds. Arixtra is contraindicated in patients weighing less than 110 pounds and patients with severe renal impairment (creatinine clearance < 30 mL/min). The major adverse effect of Arixtra is serious bleeding. The labeling for this product includes a black box warning stating that Arixtra is not to be used in connection with spinal anesthesia or spinal puncture; there is a risk for developing a spinal or epidural hematoma, which can result in long-term or permanent paralysis. Arixtra is available as a 2.5-mg injection.

INVANZ

The FDA granted approval to Merck and Co., Inc (Whitehouse Station, NJ) to market Invanz (ertapenem sodium), a new once-a-day injectable antibiotic for the treatment of moderate to severe infections in adults caused by common gram-positive and gram-negative aerobic and anaerobic bacteria. Efficacy, safety, and tolerability of Invanz were evaluated in more than 1900 patients enrolled in 13 multicenter clinical trials comparing Invanz to either ceftriaxone or piperacillin/tazobactam. The studies evaluated the overall clinical and microbiological response to Invanz in 5 infectious disease categories. The primary analysis for all the studies was assessment of response to treatment at prespecified, posttherapy follow-up visits. Therapy with Invanz ranged from 3 to 14 days. The overall safety and tolerability profile of Invanz was comparable to that of ceftriaxone and piperacillin/tazobactam. Invanz is contraindicated in patients with known hypersensitivity to any component of the product or to other drugs in the same class and patients who have had anaphylactic reactions to β-lactams. Intramuscularly administered Invanz should not be used in patients with known hypersensitivity to local anesthetics of the amide type. The most common adverse effects associated with Invanz are diarrhea, infused vein complications, nausea, headache, and vaginitis. Invanz is given as a 1-g dose, once daily, by intravenous infusion or intramuscular injection.

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

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