

Drugs recently approved or pending approval

ACTIQ

The United States Food and Drug Administration approved marketing of Actiq (oral transmucosal fentanyl citrate) by Anesta (Salt Lake City, UT). Actiq is indicated for the management of breakthrough cancer pain in patients with malignancies who are already receiving and are tolerant to opioid therapy for their underlying persistent cancer pain. Actiq, a solid formation of fentanyl citrate on a plastic handle, is designed to dissolve slowly (over a 15-minute period) in the mouth. Drug efficacy was evaluated in clinical trials involving opioid-tolerant adult cancer patients with breakthrough cancer pain ($n = 257$). In two dose-titration studies, 95 of 127 patients (75%) titrated to a successful dose of Actiq within the dose range (200, 400, 600, 800, 1200, or 1600 μg). A "successful" dose was defined as a dose at which one unit of Actiq could be used consistently for at least 2 consecutive days without unacceptable side effects. In a double-blind placebo-controlled study, 92 of 130 patients (71%) titrated to a successful dose of Actiq that produced significantly more pain relief compared with placebo at 15, 30, 45, and 60 minutes postadministration. Actiq is contraindicated in the management of acute or postoperative pain and in patients who are not tolerant to opioid therapy. Adverse events associated with Actiq are typical opioid side effects such as nausea, dizziness, somnolence, vomiting, asthenia, and headache. After an initial dose of 200 μg of Actiq, doses should be titrated to provide adequate pain relief with minimal side effects. Once the proper dose has been determined, consumption should be limited to four or fewer units of Actiq per day.

PRECOSE

The Food and Drug Administration approved Precose (acarbose tablets) by Bayer (West Haven, CT), in combination with insulin or metformin, as treatment to lower blood glucose levels in patients with type 2 diabetes mellitus whose hyperglycemia cannot be managed by diet alone. Precose was previously indicated alone or in combination with sulfonylureas for these patients. Treatment efficacy of the new indication was measured in placebo-controlled, double-blind, randomized studies; reduction in HbA1c and 1-hour postprandial glucose levels was the primary end point for all trials. In one study, patients ($n = 147$) were randomized to placebo and metformin or Precose (50 to 100 mg three times daily) and metformin. After placebo subtraction, the Precose arm showed a

-0.65 % change in HbA1c levels and a -34.3 mg/dL improvement of 1-hour postprandial glucose levels. In another study, patients ($n = 145$) were randomized to placebo and insulin or Precose (50 to 100 mg three times daily) and insulin. After placebo subtraction, the Precose arm showed a -0.69% change in HbA1c levels and a -36 mg/dL improvement of 1-hour postprandial glucose levels. Precose is contraindicated in patients with diabetic ketoacidosis or cirrhosis as well as in patients with inflammatory bowel disease, colonic ulceration, or other intestinal diseases. Possible adverse reactions associated with Precose include flatulence, diarrhea, and abdominal pain. Dosage of Precose must be individualized based on effectiveness and tolerance and should not exceed the maximum recommended dose of 100 mg three times daily.



MICARDIS

Boehringer Ingelheim Pharmaceuticals (Ridgefield, CT) received approval to market Micardis (telmisartan) for the once-daily treatment of hypertension. The drug may be used alone or in combination with other antihypertensive agents. Efficacy of Micardis was measured in several placebo-controlled clinical trials involving

patients ($n = 1773$) with mild to moderate hypertension (diastolic blood pressure of 95 to 114 mmHg). Patients ($n = 1031$) treated with Micardis showed a significant blood pressure reduction from baseline. The approximate blood pressure reduction (systolic blood pressure/diastolic blood pressure) after subtraction of placebo was 6 to 8/6 mmHg for a 20-mg dose, 9 to 13/6 to 8 mmHg for a 40-mg dose, and 12 to 13/7 to 8 mmHg for an 80-mg dose. Doses larger than 80 mg did not appear to cause additional decreases in blood pressure. Blood pressure reduction occurred after the first dose of Micardis, with maximal reduction occurring at approximately 4 weeks. Upon cessation of treatment with Micardis, blood pressure gradually returned to baseline values over a period of several days to 1 week. Adverse reactions associated with Micardis may include upper respiratory infection, back pain, sinusitis, diarrhea, and pharyngitis. The recommended dose is 20 to 80 mg/day, depending on the patient.

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