

Drugs recently approved or pending approval

AVANDAMET

GlaxoSmithKline of Research Triangle Park, NC, received approval from the US Food and Drug Administration (FDA) to market Avandamet (rosiglitazone maleate and metformin hydrochloride) tablets to improve glycemic control in patients with type 2 diabetes mellitus already treated with rosiglitazone and metformin as separate tablets or who are inadequately controlled on a metformin-only regimen. No clinical efficacy trials have been conducted with Avandamet; however, studies using the separate components have established safety and efficacy. In a 26-week, randomized, double-blind, placebo/active-controlled study, 339 patients with type 2 diabetes mellitus who were inadequately controlled on 2.5 g/day of metformin randomly received rosiglitazone 4 mg once daily, rosiglitazone 8 mg once daily, or placebo in addition to metformin. A statistically significant improvement in fasting plasma glucose and hemoglobin A_{1c} was shown in patients treated with either combination of metformin and rosiglitazone versus patients continued on metformin alone. Avandamet is contraindicated in patients with renal disease or dysfunction, congestive heart failure requiring pharmacologic treatment, hypersensitivity to rosiglitazone or metformin, and acute or chronic metabolic acidosis. Avandamet should not be used with insulin. Adverse effects may include upper respiratory tract infection, diarrhea, hypoglycemia, anemia, and edema. The dosage of Avandamet should be individualized based on efficacy and tolerability while not exceeding the maximum recommended daily dose of rosiglitazone 8 mg/metformin 2000 mg.



PEGASYS

The FDA granted approval to Hoffmann-La Roche Inc of Nutley, NJ, to market Pegasys (peginterferon alfa-2a) for the treatment of adults with chronic hepatitis C virus (HCV) infection who have compensated liver disease and have not previously received interferon alfa. The drug's safety and efficacy were assessed in 3 randomized, open-label, active-controlled clinical studies involving treatment-naive adults with compensated liver disease and detectable HCV. All patients received therapy by subcutaneous (sc) injection for 48 weeks and were followed for an additional 24 weeks. In study 1, patients (n = 630) received either Roferon-A (interferon alfa-2a) 3 MIU thrice weekly, Pegasys 135 µg once weekly, or Pegasys 180 µg once weekly. In study 2, patients (n = 526) received either Roferon-A 6 MIU thrice weekly for 12 weeks and then 3 MIU thrice weekly for 36 weeks or Pegasys 180 µg once weekly. In study 3, patients

(n = 269) received Roferon-A 3 MIU thrice weekly, Pegasys 90 µg once weekly, or Pegasys 180 µg once weekly. In all 3 studies, treatment with Pegasys 180 µg resulted in significantly more responding patients, compared with treatment with Roferon-A. Pegasys is contraindicated in neonates and infants and in patients with hypersensitivity to any of its components, autoimmune hepatitis, or decompensated hepatic disease. The most common adverse effects of the drug include headache, fatigue, myalgia, pyrexia, rigors, and psychiatric reactions (eg, depression, irritability). The recommended dosage of Pegasys is 180 µg once weekly for 48 weeks by sc administration in the abdomen or thigh.

SUBOXONE AND SUBUTEX

The FDA has approved marketing of Suboxone (buprenorphine hydrochloride/naloxone hydrochloride) and Subutex (buprenorphine hydrochloride) sublingual tablets by Reckitt Benckiser Pharmaceuticals, Inc, of Richmond, VA, for the treatment of opioid dependence. Efficacy of the drugs was evaluated by a double-blind, placebo- and active-controlled study in which 326 heroin-addicted subjects were randomly assigned to receive Suboxone 16 mg daily, Subutex 16 mg daily, or placebo. Subjects randomized to either active treatment first received an 8-mg Subutex tablet on day 1, followed by two 8-mg Subutex tablets on day 2. On day 3, those randomized to receive Suboxone were switched to the combination tablet. Results showed that the percentage of thrice-weekly urine samples that were negative for nonstudy opioids was statistically higher for patients in both the Suboxone and Subutex groups than in the placebo group. Both drugs are contraindicated in patients with known hypersensitivity. The most commonly reported adverse effects are headache, withdrawal syndrome, pain, nausea, and sweating. When taken sublingually, Suboxone and Subutex have similar clinical effects and are interchangeable. Subutex is preferred for induction and Suboxone for maintenance. The recommended target dose of Suboxone is 16 mg daily. The drugs can be prescribed by office-based physicians who complete a mandatory 8-hour (minimum) training session and obtain a waiver allowing them to prescribe certain controlled substances.

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

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