

Drugs recently approved or pending approval

TRILEPTAL

Approval was granted to Novartis Pharmaceuticals Corporation (East Hanover, NJ) to market an oral suspension formulation of Trileptal (oxcarbazepine) for use as monotherapy or adjunctive therapy in the treatment of partial seizures in adults with epilepsy and as adjunctive therapy in the treatment of partial seizures in children age 4 to 16 years with epilepsy. Four randomized, double-blind, multicenter studies evaluated Trileptal's efficacy as monotherapy. In one study, untreated patients (n = 67) with newly diagnosed and recent-onset partial seizures were randomized to placebo or Trileptal (300 mg twice daily titrated over 6 days to 600 mg twice daily, followed by maintenance therapy for 84 days). The study's primary endpoint was comparison of time to first seizure. According to Kaplan-Meier estimates, the difference between the 2 treatment groups was statistically significant in favor of Trileptal. Efficacy of Trileptal as adjunctive therapy was evaluated in 2 randomized, double-blind, multicenter studies. In these studies, patients taking 1 to 3 antiepileptic drugs concurrently were stabilized on the optimum dosages of those drugs in an 8-week baseline phase. Patients who experienced at least 8 partial seizures during that phase were randomized to placebo or Trileptal; treatment duration was 14 weeks for pediatric patients and 24 weeks for adult patients. The study's primary endpoint was a comparison of the percentage change from baseline in frequency of partial seizures. The results were statistically significant in favor of the Trileptal group. The most common adverse events associated with Trileptal include dizziness, somnolence, diplopia, fatigue, nausea, and vomiting. Trileptal oral suspension should be given twice daily with or without food. The recommended daily dose depends on the type of therapy (monotherapy or adjunctive) and patient age and weight.



TWINRIX

GlaxoSmithKline (Philadelphia, PA) received approval to market Twinrix (Hepatitis A Inactivated & Hepatitis B [Recombinant] Vaccine) for active immunization of persons age 18 years or older against disease caused by hepatitis A virus (HAV) and infection by all known subtypes of hepatitis B virus (HBV). One of 11 clinical trials evaluating efficacy of Twinrix around the world was an open, randomized, multicenter comparative trial conducted in a US population. Participants (N = 533) received either Twinrix on a 0-, 1-, 6-month schedule, or Havrix (Hepatitis A Vaccine, Inactivated) on a 0-, 6-month schedule plus Engerix-B (Hepatitis B Vaccine [Recombinant])

on a 0-, 1-, 6-month schedule, administered concurrently in opposite arms. Results demonstrated that the patients in the Twinrix group had antibody responses similar to those of participants receiving monovalent hepatitis A and B vaccines separately over the same time period. Seroconversion against HAV and seroprotection against HBV in the Twinrix group were 99.6% and 95.1%, respectively, and in the Havrix plus Engerix-B group were 99.3% and 92.2%, respectively. The most common adverse events associated with Twinrix include soreness at the injection site, headache, and fatigue. Primary immunization for adults consists of 3 doses of Twinrix, given on a 0-, 1-, 6-month schedule. Twinrix should be administered by intramuscular injection, in the deltoid region in adults.

YASMIN

The US Food and Drug Administration has approved marketing of Yasmin (drospirenone and ethinyl estradiol) by Berlex Laboratories (Montville, NJ) for the prevention of pregnancy in women who elect to use an oral contraceptive. In clinical efficacy studies of up to 2 years' duration, 2629 women (mean age, 25.5 \pm 4.7 years) completed 33,160 cycles of Yasmin use without any other contraception. Results proved that Yasmin is more than 99% effective in preventing pregnancy, with only 1 pregnancy occurring in 3201 cycles of 326 Yasmin users. Trials also found that Yasmin offers excellent menstrual cycle control with a low rate of spotting and breakthrough bleeding. Yasmin is contraindicated in women with conditions that predispose to hyperkalemia (ie, renal insufficiency, hepatic dysfunction, adrenal insufficiency) or with thromboembolic disorders. The most common adverse events reported with use of Yasmin include headache, nausea, breast tenderness, abdominal pain, bleeding between menstrual periods, and weight gain. Yasmin consists of 21 yellow tablets of a monophasic combined hormonal preparation plus 7 white inert tablets. The dosage of Yasmin is 1 yellow tablet daily for 21 consecutive days, followed by 7 white inert tablets per menstrual cycle. A patient should begin taking Yasmin either on the first day of her menstrual period or on the first Sunday after the onset of her period.

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.

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