

Drugs recently approved or pending approval

CELEBREX

The United States Food and Drug Administration approved marketing of Celebrex (celecoxib) by GD Searle & Co. (Chicago, IL) and Pfizer (New York, NY). Celebrex is indicated for the treatment of signs and symptoms of osteoarthritis (OA) and adult rheumatoid arthritis (RA). Three 12-week studies compared Celebrex (100 mg or 200 mg twice daily), naproxen (500 mg twice daily), and placebo in the treatment of patients with OA of the knee and hip. In all three studies, the Celebrex arms demonstrated significant pain reduction compared with the placebo arms. The Celebrex arms showed no significant difference in pain relief compared with the naproxen arms. Similar studies compared the effectiveness of Celebrex (100 mg or 200 mg twice daily), naproxen (500 mg twice daily), and placebo in the reduction of joint tenderness, pain, and swelling associated with RA. The Celebrex arms showed significantly more pain relief compared with the placebo arms and no significant difference in pain relief compared with the naproxen arms. In randomized controlled studies, Celebrex was associated with significantly fewer endoscopic ulcers compared with naproxen and ibuprofen. Celebrex is contraindicated in patients who have experienced allergic reactions to sulfonamides, aspirin, or nonsteroidal anti-inflammatory drugs. Potential adverse reactions to Celebrex include headache, dyspepsia, upper respiratory tract infection, and diarrhea. The recommended dose of Celebrex for treatment of the signs and symptoms of OA is 200 mg once daily or 100 mg twice daily. For relief from adult RA signs and symptoms, the recommended dose is 100 mg to 200 mg twice daily.



PLETAL

Otsuka America Pharmaceutical (Rockville, MD) received approval to market Pletal (cilostazol). The drug is the first new compound in more than 15 years indicated for the reduction of symptoms of intermittent claudication, as measured by increased walking distance. Efficacy of Pletal was evaluated in eight randomized, placebo-controlled, double-blind studies. Patients with stable intermittent claudication were randomized to 50 mg of Pletal twice daily ($n = 303$), 100 mg of Pletal twice daily ($n = 998$), or placebo ($n = 973$). Trial duration was 12 to 24 weeks. Patients in both Pletal arms experienced statistically significant improvement in

maximal walking distance compared with the placebo arm. In the Pletal arm receiving 100 mg twice daily, the range of improvement in maximal walking distance, expressed as the percent mean and median change from baseline, was 28% to 100% and 17% to 72%, respectively. For the placebo arm, the respective changes were -10% to 30% and -2% to 29%. Pletal is contraindicated in patients with congestive heart failure of any severity. Adverse events associated with Pletal include headache, diarrhea, and infection. The recommended dosage of Pletal is 100 mg twice daily at least 30 minutes before or 2 hours after meals.

PROVIGIL

The Food and Drug Administration granted approval to Cephalon (West Chester, PA) to market Provigil (modafinil). Provigil is the first new non-amphetamine drug in 40 years indicated to improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy. Two placebo-controlled, double-blind, multi-center studies measured Provigil's effectiveness. Patients who met the International Classification of Diseases, 9th Revision, and the American Sleep Disorders Association criteria for narcolepsy were given Provigil (200 mg/day or 400 mg/day) or placebo for 9 weeks. The primary endpoints of both studies were improvement in the ability to stay awake as assessed by the Maintenance of Wakefulness Test (MWT) and the change in overall disease status as measured by the Clinical Global Impression of Change (CGI-C). Patients in both Provigil arms showed statistically significant improvement in the MWT and the CGI-C compared with the placebo arm. The studies' secondary endpoints included improvement in the Multiple Sleep Latency Test (MSLT) and the Epworth Sleepiness Scale (ESS). Patients in both Provigil arms experienced a significant decrease in the propensity to fall asleep as measured by the MSLT and a significant decrease in patient-assessed levels of daytime sleepiness according to the ESS. The most common adverse events associated with Provigil include headache, nausea, rhinitis, nervousness, and diarrhea. The recommended dose of Provigil is 200 mg/day as a single dose in the morning.

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.

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