

Drugs recently approved or pending approval

ADDERALL XR

Shire Pharmaceuticals Group plc (Florence, KY) received approval to market Adderall XR (mixed salts of a single-entity amphetamine product) capsules, an extended-release formulation of Shire's Adderall, for the treatment of attention-deficit/hyperactivity disorder (ADHD). Efficacy of Adderall XR was evaluated in a double-blind, placebo-controlled study conducted in children 6 to 12 years of age (N = 584) who met *DSM-IV* criteria for ADHD. Patients were randomized to receive fixed doses of 10, 20, or 30 mg of Adderall XR or placebo, taken once daily in the morning for 3 weeks. Significant improvements in patient behavior, based on teacher ratings of attention and hyperactivity, were observed for all patients taking Adderall XR, compared with patients receiving placebo, for all 3 weeks. Adderall XR is contraindicated in patients with advanced arteriosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism, glaucoma, agitated states, or history of drug abuse and in patients who have taken a monoamine oxidase inhibitor within the previous 14 days. Common adverse effects associated with Adderall XR include anorexia, insomnia, abdominal pain, emotional lability, and nervousness. The recommended starting dosage of Adderall XR for patients 6 years

of age and older is 10 mg once daily in the morning. Daily dosage may be raised in increments of 10 mg at weekly intervals, not to exceed 30 mg daily. Adderall XR capsules may be taken whole, or the capsule may be opened and the entire contents sprinkled on applesauce and consumed immediately.

CELEBREX

Approval was granted to Pharmacia Corporation (Peapack, NJ) and Pfizer Inc (New York, NY) to market Celebrex (celecoxib) capsules for 2 new indications—the management of acute pain and treatment of primary dysmenorrhea in adults. Celebrex is already indicated for relief of pain and inflammation of osteoarthritis and rheumatoid arthritis; it is also approved to reduce the number of adenomatous colorectal polyps in cases of familial adenomatous polyposis, as an adjunct to usual care. Approval of Celebrex for its new indications followed a review of data from clinical studies involving more than 1700 patients with post-oral surgery pain, musculoskeletal pain, post-orthopaedic surgery pain, or primary dysmenorrhea in which patients rated their pain as moderate to severe. Single doses of Celebrex (400 mg initially) provided pain relief within 60 minutes. Patients who have experienced asthma, urticaria, or allergic-type reactions

after taking aspirin or other nonsteroidal anti-inflammatory drugs should not take Celebrex. Celebrex should be used with caution in patients with fluid retention, hypertension, or heart failure. The most common adverse effects associated with Celebrex are dyspepsia, diarrhea, and abdominal pain. The recommended dosage of Celebrex for the management of acute pain or treatment of primary dysmenorrhea is 400 mg initially, followed by an additional 200-mg dose if needed on the first day. On subsequent days, the recommended dosage is 200 mg twice daily as needed.

NUVARING

The US Food and Drug Administration has approved marketing of NuvaRing (etonogestrel/ethinyl estradiol vaginal ring) by Organon Inc (West Orange, NJ) for the prevention of pregnancy in women. NuvaRing is a flexible, transparent ring that provides month-long contraceptive protection by delivering a continuous dose of 0.120 mg of etonogestrel and 0.015 mg of ethinyl estradiol daily over a 21-day period. The safety and efficacy of NuvaRing has been studied in worldwide clinical trials in which 2322 women were exposed to 23,289 cycles of NuvaRing. In 2 large clinical trials of 13 cycles of NuvaRing use, pregnancy rates were between

1 and 2 per 100 women-years of use. NuvaRing is contraindicated in patients with the following conditions: thrombophlebitis or thromboembolic disorders, cerebral vascular or coronary artery disease, severe hypertension, diabetes with vascular involvement, headaches with neurologic symptoms, known or suspected carcinoma of the breast or endometrium, undiagnosed abnormal genital bleeding, jaundice, hepatic tumors, active liver disease, known or suspected pregnancy, and heavy smoking (≥ 15 cigarettes daily) in women older than 35 years. The most common adverse effects of NuvaRing use include vaginitis, headache, upper respiratory tract infection, leukorrhea, sinusitis, weight gain, and nausea. A woman inserts NuvaRing into her vagina on or before the fifth day of her menstrual period, and it should remain in place continuously for 3 weeks. The ring is removed for a 1-week break, during which a withdrawal bleed usually occurs. A new ring is inserted 1 week after the last ring was removed.

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.

