

Drugs recently approved or pending approval

AVELOX

Bayer Corporation (West Haven, CT) received approval to market Avelox (moxifloxacin hydrochloride) Tablets as a once-daily treatment for adults with uncomplicated skin and skin structure infections (uSSSIs) caused by *Staphylococcus aureus* or *Streptococcus pyogenes*. Avelox is also indicated for the treatment of acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, and community-acquired pneumonia. A randomized, double-blind, controlled trial compared the efficacy of Avelox (400 mg once daily for 7 days) with cephalexin HCl (500 mg 3 times daily for 7 days) in the treatment of mild to moderate acute uSSSIs. The study showed that Avelox was clinically and bacteriologically equivalent in efficacy to cephalexin in eradicating *Staphylococcus aureus* and *Streptococcus pyogenes*. The percentage of patients treated for uncomplicated abscesses was 30%; furuncles, 8%; cellulitis, 16%; impetigo, 20%; and other skin infections, 26%. Adjunctive procedures (incision and drainage or débridement) were performed on 17% of the Avelox-treated patients and 14% of the cephalexin-treated patients. Clinical success rates in evaluable patients were 89% (108/122) for Avelox and 91% (110/121) for cephalexin HCl. Avelox should be avoided in patients with prolongation of the QT interval, patients with uncorrected hypokalemia, and patients receiving Class IA or Class III antiarrhythmic agents. The most common adverse events associated with Avelox are nausea, diarrhea, dizziness, headache, abdominal pain, and vomiting. The dosing regimens for Avelox are as follows: 400 mg once daily for 7 days for uSSSIs; 400 mg once daily for 10 days for acute bacterial sinusitis and community-acquired pneumonia; and 400 mg once daily for 5 days for acute bacterial exacerbation of chronic bronchitis.

CLIMARA

The US Food and Drug Administration approved marketing of a new, expanded indication for Climara (estradiol transdermal system) by Berlex Laboratories, Inc (Montville, NJ). Climara 0.025 mg daily has been recommended as the starting dose for the treatment of menopausal symptoms and the prevention of osteoporosis. In a bioavailability study, Climara 0.025 mg was compared with Climara 0.05 mg as a reference. The maximum, minimum, and average concentrations of mean serum estradiol for Climara 0.025 mg were 32, 17, and 22 pg/mL, respectively. The maximum, minimum, and average concentrations of mean serum estradiol for Climara 0.05 mg were 71, 29, and 41 pg/mL, respectively. Climara is contraindicated for use by

individuals with known or suspected pregnancy, undiagnosed abnormal genital bleeding, breast cancer, estrogen-dependent neoplasia, active thrombophlebitis, or thromboembolic disorders. The most common adverse reactions associated with the use of Climara include skin irritation at the application site, changes in vaginal bleeding patterns, breast tenderness and enlargement, nausea, vomiting, headache, and dizziness. The Climara system should be applied at a 7-day dosing interval. The adhesive side of the Climara system should be placed on a clean, dry area of the lower abdomen or the upper quadrant of the buttock. It should not be applied to the breasts. The sites of application must be rotated, with an interval of at least a week between applications to a particular site.

REMINYL

Approval was granted to Janssen Pharmaceutica Products, LP (Titusville, NJ) to market Reminyl (galantamine hydrobromide) tablets for the treatment of mild to moderate dementia of the Alzheimer's type. Data from 4 placebo-controlled, double-blind clinical trials involving more than 2650 patients confirm Reminyl's efficacy in patients' daily function and ability to think. In studies ranging from 12 to 26 weeks, patients' abilities related to memory, orientation, reasoning, and language were assessed using the cognitive portion of the Alzheimer's Disease Assessment Scale. The results

consistently demonstrated that more patients taking Reminyl showed significant improvement in cognitive performance than did those receiving placebo. Efficacy of Reminyl was also measured with the Clinician's Interview-Based Impression of Change plus Caregiver Information (CIBIC-plus), which provides an overall assessment of patient functioning, including behavior, organized thinking, and activities of daily living. The CIBIC-plus results from all studies showed that the overall scores for patients taking Reminyl were statistically superior to those of the placebo group. The most common adverse effects of Reminyl are nausea, vomiting, diarrhea, anorexia, and weight loss. The recommended starting dose of Reminyl is 4 mg twice daily, preferably with morning and evening meals. After a minimum of 4 weeks of treatment, the dose should be increased to 8 mg twice daily. A further increase to 12 mg twice daily should be attempted only after at least 4 weeks at the previous dose.



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

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