

### Drugs recently approved or pending approval

#### AUGMENTIN ES-600

Approval was granted to GlaxoSmithKline (Philadelphia, PA) to market Augmentin ES-600 (amoxicillin/clavulanate potassium), a new high-dose formulation of Augmentin. Augmentin ES-600 is indicated for the treatment of pediatric patients with recurrent or persistent acute otitis media caused by *Streptococcus pneumoniae*, *Haemophilus influenzae*, or *Moraxella catarrhalis* characterized by the following risk factors: age  $\leq 2$  years and day care attendance. A noncomparative, open-label study assessed the bacteriologic and clinical efficacy of Augmentin ES-600 given twice daily for 10 days in 521 pediatric patients (age 3 to 50 months) with acute otitis media. Prior to receiving Augmentin ES-600, all patients underwent tympanocentesis to obtain middle ear fluid for bacteriologic evaluation. Patients from whom *S. pneumoniae* was isolated had a second tympanocentesis 4 to 5 days after the start of therapy. Clinical assessments were planned for all patients during treatment (4 to 6 days after starting therapy), as well as 2 to 4 days posttreatment and 15 to 18 days posttreatment. Results showed that Augmentin ES-600 eradicated 97% of penicillin-resistant *S. pneumoniae* bacteria, 100% of penicillin-susceptible and intermediate-resistant *S. pneumoniae* bacteria, 95% of *H. influenzae* bacteria, and 100% of *M. catarrhalis* bacteria, including drug-resistant strains. Symptoms of middle ear infections were improved or eliminated in the majority of patients. The most common adverse events associated with Augmentin ES-600 are diaper rash, diarrhea, vomiting, and moniliasis. The recommended dosage of Augmentin ES-600 is 90 mg/kg body weight per day divided every 12 hours, administered for 10 days. Augmentin ES-600 should be taken at the start of a meal.

#### ESTROSTEP

Pfizer, Inc. (New York, NY) received approval to market Estrostep (norethindrone acetate/ethinyl estradiol) for a new indication. Previously indicated for the prevention of pregnancy in women, Estrostep is now indicated for the treatment of moderate acne vulgaris in female patients 15 years of age and older who have no known contraindications to oral contraceptive therapy, desire oral contraception, have achieved menarche, are unresponsive to topical anti-acne medications, and plan to remain on Estrostep for at least 6 months. Two randomized, double-blind, placebo-controlled, multicenter studies evaluated Estrostep in the treatment of acne vulgaris. The mean age at enrollment for both groups was 24 years, and a total of 295 sub-

jects received Estrostep while 296 received placebo. At 6 months, results showed a statistically significant difference between Estrostep and placebo in terms of mean change from baseline in lesion counts. Estrostep users had a 43% reduction in the number of acne lesions after 6 months of treatment, and placebo users had a 32% reduction in the number of acne lesions during the same period. Each trial also demonstrated overall treatment success in the investigator's global evaluation. Estrostep is contraindicated in women who have thrombophlebitis or thromboembolic disorders, cerebral vascular or coronary artery disease, carcinoma of the breast or endometrium, or undiagnosed abnormal genital bleeding. The most frequently reported side effects associated with Estrostep use are nausea, vomiting, abdominal cramps and bloating, breakthrough bleeding, and spotting. Estrostep is available in 21-day and 28-day dosing regimens.



#### VALTREX

The US Food and Drug Administration has approved a supplemental new drug application from GlaxoSmithKline (Philadelphia, PA) that allows patients to effectively treat recurrent episodes of genital herpes with a 3-day regimen of Valtrex (valacyclovir hydrochloride) caplets versus the standard 5-day regimen. Valtrex is indicated for the treat-

ment or suppression of genital herpes. The efficacy of the 3-day regimen was evaluated in 3 double-blind trials (2 of them placebo controlled) in immunocompetent adults with recurrent genital herpes. Patients self-initiated therapy within 24 hours of the first sign or symptom of a recurrent episode of genital herpes. In one study, patients were randomized to receive Valtrex 500 mg twice daily for 5 days ( $n = 398$ ) or Valtrex 500 mg twice daily for 3 days (and matching placebo twice daily for 2 additional days) ( $n = 402$ ). The median time to lesion healing was approximately 4.5 days, and the median time to cessation of pain was approximately 3 days in both treatment groups. The most common adverse effects associated with Valtrex are headache, nausea, and abdominal pain. The recommended dosage of Valtrex for the treatment of recurrent genital herpes is 500 mg twice daily for 3 days. Dosage reduction is recommended when administering Valtrex to patients with renal impairment.

*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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