

### Drugs recently approved or pending approval

#### MAXIPIME

The United States Food and Drug Administration granted Dura Pharmaceuticals (San Diego, CA) approval to market Maxipime (cefepime hydrochloride) for injection, for use in pediatric patients age 2 months to 16 years. Maxipime is indicated as empiric therapy for febrile neutropenic patients and for the treatment of the following infections: moderate to severe pneumonia caused by *Streptococcus pneumoniae*, *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, or *Enterobacter* species; moderate to severe urinary tract infections caused by *Escherichia coli* or *K. pneumoniae*; mild to moderate urinary tract infections caused by *Proteus mirabilis*; uncomplicated skin and skin structure infections caused by *Staphylococcus aureus* (methicillin-susceptible strains only) or *Streptococcus pyogenes*; and complicated intra-abdominal infections (in combination with metronidazole) caused by *E. coli*, viridans group streptococci, *Pseudomonas aeruginosa*, *K. pneumoniae*, *Enterobacter* species, or *Bacteroides fragilis*. Efficacy of the drug was evaluated in clinical trials that compared Maxipime monotherapy with ceftazidime monotherapy. Results showed Maxipime to be therapeutically equivalent to ceftazidime. Safety in patients age 2 months to 16 years was established in additional pharmacokinetic and safety trials. Potential adverse reactions associated with Maxipime include pain or inflammation at the injection site, rash, diarrhea, or nausea. Pediatric dosage, means of administration, and treatment duration depend on the diagnosis.



#### DITROPAN XL

The Food and Drug Administration approved marketing of Ditropan XL (oxybutynin chloride) by Alza Corporation (Palo Alto, CA). Ditropan XL is the first and only once-daily controlled-release treatment for overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency. Efficacy of Ditropan XL was measured in four studies involving patients with urge or mixed incontinence as evidenced by more than six urge incontinence episodes per week and 10 or more micturitions per day. In one study, patients received Ditropan XL ( $n = 34$ ) or placebo ( $n = 16$ ). In the Ditropan XL arm, the number of urge urinary incontinence episodes was reduced by 16 episodes/week compared with a reduction of 8 episodes/week in the placebo arm. In two studies comparing Ditropan XL (controlled release oxybutynin) with oxybutynin, the reduction in the

number of incontinence episodes ranged from 15 to 18/week in the Ditropan XL arms and 14 to 19/week in the oxybutynin arms, demonstrating comparable efficacy. Ditropan XL is contraindicated in patients who have or are at risk for urinary retention, gastric retention, or uncontrolled narrow-angle glaucoma. Adverse events associated with Ditropan XL include dry mouth, constipation, drowsiness, and headache. The recommended starting dose of Ditropan XL is 5 mg once daily, taken with or without food.

#### CRIXIVAN

Merck & Co. (West Point, PA) received approval to market a new 333-mg capsule of Crixivan (indinavir sulfate). Crixivan is indicated in combination with other antiretroviral agents for the treatment of HIV infection. The new capsule strength of Crixivan is more convenient for patients who are following combination antiretroviral programs. Efficacy of the drug was evaluated in several multicenter, randomized trials. In one study, zidovudine-experienced HIV-infected patients were randomized to zidovudine and lamivudine ( $n = 579$ ) or Crixivan, zidovudine, and lamivudine ( $n = 577$ ) to compare the effects of the combination therapies on progression to an AIDS-defining illness or death. Six percent of the patients in the Crixivan/zidovudine/lamivudine arm progressed to an AIDS-defining illness or death compared with 11% in the zidovudine/lamivudine arm. In a second study, antiretroviral-naïve HIV-infected patients were randomized to Crixivan ( $n = 332$ ), zidovudine ( $n = 332$ ), or Crixivan and zidovudine ( $n = 332$ ). Eight percent of the patients in the Crixivan arm progressed to AIDS-defining illness or death compared with 6% in the Crixivan/zidovudine arm and 19% in the zidovudine arm. Crixivan is contraindicated in patients who are using the following drugs: terfenadine, cisapride, astemizole, triazolam, midazolam, or ergot derivatives. Adverse reactions associated with Crixivan may include nausea, abdominal pain, headache, and diarrhea. The recommended dosage of Crixivan is 800 mg orally every 8 hours taken 1 hour before or 2 hours after a meal.

Compiled from press reports and pharmaceutical company press releases. For more information, contact Deidre Yoder, Hospital Physician, 125 Stratford Avenue, Suite 220, Wayne, PA 19087-3391.