



April 9, 2008

Dear Colleague,

In April 2008, cefixime 400 milligram tablets will again be available for distribution in the United States. A single dose of cefixime 400 mg tablets is the only *oral* treatment for uncomplicated gonorrhea of the cervix, urethra or rectum recommended by the Centers for Disease Control and Prevention (CDC). Since 2002, the availability of cefixime tablets has been limited in the U.S. Lupin Pharmaceuticals, Inc., received Food and Drug Administration (FDA) approval to manufacture and market cefixime in 2004, but has only had an oral suspension form available.

The availability of cefixime 400 mg tablets increases options to treat gonorrhea, one of the most common sexually transmitted diseases in the U.S. Since April 2007, CDC has advised providers not to use fluoroquinolones (ciprofloxacin, ofloxacin, and levofloxacin) for the treatment of gonorrhea, based on data indicating widespread drug resistance in the U.S.

(www.cdc.gov/mmwr/preview/mmwrhtml/mm5614a3.htm). Consequently, the recommended treatment options for gonorrhea are limited to a single class of antibiotics, the cephalosporins. Within this class, CDC recommends ceftriaxone, available only as an injection, for all types of gonorrhea infection (genital, anal and pharyngeal). Cefixime is recommended for genital and rectal gonorrhea. CDC also recommends that persons in whom gonococcal infection is diagnosed should be treated for possible coinfection with *Chlamydia trachomatis* if chlamydial infection has not been ruled out. Guidance and updates on gonorrhea treatment are available at www.cdc.gov/std/treatment/.

The renewed availability of cefixime tablets in the U.S. also facilitates expedited partner therapy (EPT) in states where EPT is permissible. EPT is the delivery of medications or prescriptions by persons infected with gonorrhea to their sex partners. Clinicians provide patients with sufficient medications directly or via prescription for the patients' partners. EPT should not replace other routine notification activities and should not be used for men who have sex with men (MSM) or partners who require clinical evaluation, such as those with symptoms. More information about EPT is available at www.cdc.gov/std/ept/.

Once supplies of cefixime are available for shipment, a Notice to Readers will be published in the MMWR, and CDC will issue a press release, targeted to health professionals in the private sector. We will send our state and local health department partners notification of the publication of the MMWR and copies of the press release so you can be prepared to respond to questions from health care providers in your jurisdictions. For information on how to obtain cefixime, contact Lupin Pharmaceuticals, Inc., at (866) 587-4617 (cefixime 400 mg tablets NDC# 27437-201-08).

The renewed availability of cefixime in oral form is a positive step in controlling the spread of this serious disease that affects roughly 700,000 Americans each year. CDC recommends that effective treatment for gonorrhea and partner management also be combined with targeted screening of populations at risk. CDC continues to call for research and development of new and effective gonorrhea drugs and for increased efforts to monitor for drug resistance, which are also critical measures for controlling gonorrhea.

Sincerely,

John M. Douglas, Jr., MD
Director, Division of STD Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention