Information for Healthcare Professionals

Gatifloxacin
(marketed as TEQUIN)

FDA ALERT [3/2006]: On February 15, 2006, Bristol Myers Squibb (BMS) issued a Dear Healthcare Professional (DHCP) letter to U.S. physicians announcing an update to the U.S. labeling for TEQUIN (gatifloxacin) Tablets and Injection. The update includes labeling changes to strengthen the existing WARNING on hypoglycemia and hyperglycemia and adds a CONTRAINDICATION for use in diabetic patients. Serious reports of hypoglycemia and hyperglycemia continue to occur in patients both with and without a history of diabetes. These events can occur throughout the course of TEQUIN therapy. The labeling has also been updated to identify other risk factors for developing hypoglycemia and hyperglycemia, (i.e., older age, abnormal kidney function, and other blood glucose altering medications being used at the same time) while taking TEQUIN (gatifloxacin), and includes a recommendation for close medical monitoring.

FDA will review all available data and determine whether additional changes to labeling, or other regulatory actions, are warranted.

This information reflects FDA's current analysis of data available to FDA concerning this drug. FDA intends to update this sheet when additional information or analyses become available.

To report any unexpected adverse or serious events associated with the use of this drug, please contact the FDA MedWatch program using the contact information at the bottom of this sheet.

Considerations

- Tequin is contraindicated in patients with diabetes mellitus
- In addition to diabetes, other risk factors associated with dysglycemia while taking TEQUIN include older age, renal insufficiency, and concomitant glucose-altering medications (including but not limited to hypoglycemic medications, corticosteroids, diuretics). Patients with these risk factors should be closely monitored for glucose disturbances.
- **Serious reports of hypoglycemia and hyperglycemia have also occurred in patients without a history of diabetes.** If signs and symptoms of either hypoglycemia or hyperglycemia occur in any patient being treated with TEQUIN, appropriate therapy must be initiated immediately and TEQUIN should be discontinued.

Information for Healthcare Professionals

Gatifloxacin
(marketed as TEQUIN)

Data Summary
In postmarketing experience worldwide, there have been reports of disturbances in glucose homeostasis that usually occurs within 3 days of initiating TEQUIN therapy. Most of these events were reversible although some resulted in fatal outcomes.

ADDITIONAL INFORMATION: (These are now available on MedWatch site)
http://www.fda.gov/medwatch/SAFETY/2006/safety06.htm#Tequin

February 15, 2006 Letter from BMS
http://www.fda.gov/medwatch/safety/2006/tequin_DHCP.pdf

January 2006 TEQUIN Label
http://www.fda.gov/medwatch/safety/2006/tequin_PI.pdf