



Patient Information Sheet

Gatifloxacin (marketed as Tequin)

This is a summary of the most important information about Tequin. For details, talk to your healthcare professional.

FDA ALERT [3/2006] On February 15, 2006, Bristol Myers Squibb (BMS), revised the Tequin labeling because Tequin has caused some people to have serious blood sugar problems (low blood sugar or high blood sugar).

The new Tequin label:

- **says that Tequin should not be used in patients with diabetes**
- **has stronger warnings about serious blood sugar problems**
- **tells healthcare professionals to closely monitor patients that have a higher chance for getting serious blood sugar problems with Tequin**
- **lists risk factors that give people a higher chance for getting serious blood sugar problems with Tequin such as:**
 - *older age
 - *kidney problems
 - *taking other medicines that affect blood sugar while taking Tequin

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

What Is Tequin?

Tequin is an antibiotic used to treat adults with lung, sinus, or urinary tract infections and also to treat certain sexually transmitted diseases caused by germs called bacteria. Sometimes viruses, rather than bacteria, may infect the lungs and sinuses (for example, the common cold). Tequin, like all other antibiotics, does not kill viruses.

The sexually transmitted disease called gonorrhea is treated by Tequin. Other sexually transmitted diseases including syphilis and non-gonococcal diseases are not treated by Tequin.

Who Should Not Take Tequin?

You should not take Tequin if you:

- Are allergic to Tequin or any "quinolones" such as:
 - Ciprofloxacin (CIPRO)
 - Gatifloxacin (TEQUIN, ZYMAR)
 - Levofloxacin (LEVAQUIN)
 - Lomefloxacin (MAXAQUIN)
 - Moxifloxacin (AVELOX, VIGAMOX)
 - Gemifloxacin (FACTIVE)
 - Norfloxacin (NOROXIN)
 - Ofloxacin (FLOXIN)
- Have a rare heart condition called congenital prolongation of the QTc interval. If any of your family members have this condition, tell your healthcare professional
- Have low blood potassium (hypokalemia). Low blood potassium may be caused by medicines called diuretics or "water pills"
- Are taking medicines to treat an irregular heartbeat
- Have diabetes or high blood sugar
- If you are pregnant or nursing, talk to your healthcare professional before taking

What Are The Risks?

The following are the major potential risks and side effects of Tequin therapy. However, this list is not complete.

If you have any of the following side effects, stop taking Tequin and call your doctor:

- serious blood sugar changes including low blood sugar (hypoglycemia) or high blood sugar (hyperglycemia). See FDA Alert.
- severe allergic reactions (trouble breathing; closing of the throat; swelling of the lips, tongue, or face; or hives)
- central nervous system (CNS) side effects including: seizures, dizziness, confusion, tremors, hallucinations, depression, or suicidal thoughts
- pain, inflammation, or rupture of a tendon





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Some common side effects that may occur with Tequin include:

- Nausea
- Vomiting
- Stomach pain
- Diarrhea
- Dizziness
- Headache
- Abnormal blood sugar level, too low or too high

What Should I Tell My Healthcare Professional?

Before you start taking Tequin, tell your healthcare professional if you:

- are trying to become pregnant, are already pregnant, or are breast-feeding. The effects on the unborn child and nursing infant are unknown.
- have diabetes
- have heart problems
- have or had liver problems
- have kidney problems

Can Other Medicines Or Food Affect Tequin?

Tequin and certain other medicines can interact with each other. Tell your healthcare professional about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them with you to show your healthcare professional.

Especially tell your healthcare professional if you take:

- medicine to control blood sugar (insulin, glyburide, other hypoglycemic drugs) or steroids
- medicines to treat an irregular heartbeat

- cisapride, erythromycin, antidepressant medicines, or antipsychotic medicines. These medicines may increase the chance of heart beat problems when taken with Tequin.
- medicines called diuretics or ‘water pills’ because they can sometimes cause low blood potassium
- diabetes medicines
- Videx (didanosine): Tequin should be taken 4 hours before your dose of Videx.
- antacids and multivitamins that contain zinc, magnesium, or iron. These may stop Tequin from passing into your body. Take Tequin 4 hours before taking any of these products.

What Else Should I Know?

- Do not drive or operate dangerous machines until you know how Tequin affects you. Tequin can cause dizziness.
- Avoid long exposure to sunlight. Tequin may make your skin more sensitive to sunlight. You may get severe sunburn. Call your healthcare professional if you have severe burning, redness, itching, rash, or swelling after being in the sun while taking Tequin.
- Tequin for Oral Suspension contains phenylalanine. This is important to know if you have a condition called Phenylketonuria.

Tequin Approved: 12/1999
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