

Patient Information About:

TEQUIN® (gatifloxacin)

Rx only

200-mg and 400-mg Tablets

This section contains important information about TEQUIN (gatifloxacin) that you should read before you begin treatment. This section does not list all the benefits and risks of TEQUIN and does not take the place of discussions with your doctor or healthcare provider about your medical condition or your treatment. If you have questions, talk with your healthcare provider. The medicine described here can only be prescribed by a licensed healthcare provider. Only your healthcare provider can determine if TEQUIN is right for you.

What is TEQUIN?

TEQUIN (*pronounced TEK win*) is an antibiotic used to treat lung, sinus, skin, or urinary tract infections, and also to treat certain sexually transmitted diseases caused by germs called bacteria. TEQUIN kills many of the kinds of bacteria that can infect the lungs, sinus, skin, and urinary tract and that cause certain sexually transmitted diseases. TEQUIN has been shown in a large number of clinical trials to be safe and effective for the treatment of bacterial infections.

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 diseases called syphilis or non-gonococcal disease are not treated by TEQUIN.

You should contact your doctor if you think your condition is not improving while taking TEQUIN. TEQUIN tablets are white and contain either 200 mg or 400 mg of active drug.

How and when should I take TEQUIN?

TEQUIN should be taken once a day for 1 to 14 days depending on your prescription. It should be swallowed whole and may be taken with or without food. Try to take the tablet at the same time each day.

You may begin to feel better quickly; however, in order to make sure that all bacteria are killed, you should complete the full course of medication. Do not take more than the prescribed dose of TEQUIN. Try not to miss a dose, but if you do, take it as soon as possible. If it is almost time for the next dose, skip the missed dose and continue your regular dose.

Who should not take TEQUIN?

- You should not take TEQUIN if you have ever had a severe allergic reaction to any medicine in the group of antibiotics known as "quinolones" such as AVELOX® (moxifloxacin hydrochloride), CIPRO® (ciprofloxacin) or LEVAQUIN® (levofloxacin).
- You should not take TEQUIN if you have diabetes.
- If you are pregnant or planning to become pregnant while taking TEQUIN, talk to your healthcare provider before taking this medication.
- TEQUIN is not recommended for use during pregnancy or nursing, as the effects on the unborn child or nursing infant are unknown.
- TEQUIN is not recommended for children.
- You should avoid TEQUIN if you have a rare condition known as congenital prolongation of the QTc interval. If any of your family members have this condition, you should inform your healthcare provider.
- You should avoid TEQUIN if you are being treated for heart rhythm disturbances with certain medicines such as quinidine, procainamide, amiodarone, or sotalol. Inform your healthcare provider if you are taking a heart rhythm drug.
- You should avoid TEQUIN if you have a condition known as hypokalemia (low blood potassium). Hypokalemia may be caused by medicines called diuretics such as furosemide and hydrochlorothiazide. If you are taking a diuretic you should speak with your healthcare provider.

What about other medications I am taking?

It is important to let your healthcare provider know all of the medicines that you are using, both prescription and nonprescription.

- If you have diabetes, it is important to let your healthcare provider know that you have this condition and what medications you are taking for it. Please be sure to read "**Who should not take TEQUIN?**".
- The use of TEQUIN with certain medications may cause changes in your blood sugar level. Please be sure to read "**What are the possible side effects of TEQUIN?**" to find out about disturbances of blood sugar levels.
- It is important to let your healthcare provider know if you are taking certain medicines that can have an effect on an electrocardiogram test, such as cisapride, erythromycin, some antidepressants, and some antipsychotic drugs.
- You should tell your healthcare provider if you are taking medicines called diuretics (also sometimes called water pills) such as furosemide and hydrochlorothiazide, because diuretics can sometimes cause low potassium.
- If you are taking didanosine buffered tablets or pediatric powder for oral solution, TEQUIN should be taken 4 hours before your dose of didanosine.

- Many antacids and multivitamins contain zinc, magnesium, or iron, which may interfere with the absorption of TEQUIN (gatifloxacin) and may prevent it from working properly. You should take TEQUIN 4 hours before taking these products.

What are the possible side effects of TEQUIN?

TEQUIN is generally well tolerated. The most common side effects that can occur when taking TEQUIN are usually mild and include nausea, vomiting, stomach ache, diarrhea, dizziness, and headache. You should be careful about driving or operating machinery until you are sure TEQUIN does not cause dizziness. If you notice any side effects not mentioned in this section or if you have any questions or concerns about the side effects you are experiencing, please discuss them with your healthcare provider.

Disturbances of blood sugar (both high and low) have been reported with TEQUIN, usually in diabetic patients. However, these symptoms have occurred in patients without diabetes. Certain factors, such as older age, kidney problems and the use of certain medicines, may increase your risk of having changes in your blood sugar levels while taking TEQUIN. Therefore, discuss with your healthcare provider if you have kidney problems or are taking any other medication. Discuss how to detect changes in your blood sugar with your healthcare provider and the steps you should take if you detect such changes.

In a few people, TEQUIN, like some other antibiotics, may produce a small effect on the heart that is seen on an electrocardiogram test. Although this did not cause any problems in patients who took TEQUIN in premarketing clinical trials, rare cases of abnormal heartbeat, which may be dangerous, have been reported since TEQUIN has been marketed. Contact your healthcare provider if you develop heart palpitations (fast beating) or have fainting spells.

Disturbances of blood sugar, including symptoms of high blood sugar (hyperglycemia) and low blood sugar (hypoglycemia), have been reported with TEQUIN in diabetic patients. Elderly patients with additional medical problems or taking additional medications may also be at risk for high blood sugar. If you develop low blood sugar while on TEQUIN, you should take immediate measures to increase your blood sugar, stop taking TEQUIN, and contact your healthcare provider at once. If you develop high blood sugar while on TEQUIN, you should contact your healthcare provider at once before taking additional TEQUIN. If you have diabetes or suspect that you may have diabetes, discuss how to detect changes in your blood sugar with your healthcare provider at once before taking additional TEQUIN.

TEQUIN, like other drugs in this class (quinolones), has been rarely associated with inflammation of tendons. If you experience pain, swelling, or rupture of a tendon, you should stop taking TEQUIN and call your healthcare provider.

Convulsions have been reported in patients receiving quinolone antibiotics including TEQUIN. Be sure to let your healthcare provider know if you have a history of convulsions.

TEQUIN, like other drugs in this class, has been associated with other central nervous system events including confusion, tremor, hallucinations, and depression.

Where can I get more information about TEQUIN?

This section is a summary of the most important information about TEQUIN. It does not include everything there is to know about TEQUIN. If you have any questions or problems, you should talk to your doctor or healthcare provider. There is also a leaflet (Package Insert) written for healthcare providers that your pharmacist can let you read. You may want to read this information and discuss it with your doctor or other healthcare provider. Remember, no written information can replace careful discussion with your doctor.

Remember

- Take your dose of TEQUIN once a day.
- Complete the course of medication (take all of the pills) even if you are feeling better.
- Do not use TEQUIN for another condition or give it to others.
- Store TEQUIN tablets at room temperature in a tightly sealed container.
- Throw away TEQUIN when it is outdated or no longer needed by flushing it down the toilet.
- Keep this and all medications out of reach of children.



Bristol-Myers Squibb Company

Princeton, NJ 08543 U.S.A.

E5-B0001B-01-06
Based on 51-029012-05, 1188383A3

Revised January 2006

Licensed from Kyorin Pharmaceutical Company, Limited, Tokyo, Japan