DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

APR 10 2000

Kathleen Meriwether
Senior Director
Regulatory Services
Bristol-Myers Squibb Company
777 Scudders Mill Road
Plainsboro, NJ 08536

RE: NDA 21-061/062
Tequin® (gatifloxacin) Tablets/Injection
MACMIS ID# 8782

Dear Ms. Meriwether:

It has come to the attention of the Division of Drug Marketing, Advertising, and Communications (DDMAC) that Bristol-Myers Squibb Company (BMS) is promoting its product, Tequin, in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Specifically, we refer to your current website[1] for Tequin. We request that you cease distribution and use of false and/or misleading messages in all promotional materials as outlined below.

Misleading Efficacy Claims

BMS's website provides misleading efficacy rates for Tequin. BMS states that "Tequin delivers strong clinical efficacy" and utilizes efficacy rates of "≥90% in acute bacterial exacerbation of chronic bronchitis (ABECB), 96% in acute sinusitis (sinusitis), and ≥97% in community-acquired pneumonia (CAP)." However, clinical studies used as the basis of approval for Tequin demonstrated efficacy rates of 78-88% for ABECB, 62-88% for sinusitis, and 73-90% for CAP. Therefore, BMS is overstating the efficacy rates by selectively presenting higher efficacy rates for Tequin's use in ABECB, sinusitis, and CAP.

BMS's website also misleadingly suggests that Tequin is effective against resistant pathogens with the following statement:

> *For bacteria to develop resistance against Tequin, they must develop mutations in both enzymes. Thus, the chance of susceptible bacteria to develop resistance to Tequin is extremely low.*

1 http://www.tequin.com (current as of April 7, 2000)

BMS's wording is inconsistent with the approved product labeling (APL), which states that cross-resistance has been observed between gatifloxacin and some other fluoroquinolones. Therefore, this presentation is misleading because BMS is selectively presenting information to suggest that Tequin is more effective against resistant pathogens than has been determined.

Lack of Fair Balance

BMS describes Tequin as being "safe and easy" for patients to take and as having an "excellent tolerability profile." Although BMS has disclosed the fact that Tequin has the potential to prolong the QTc interval of the electrocardiogram in certain patients, this serious safety risk is not prominently displayed within the text compared to the above safety claims. In the APL, this risk information is communicated as a bolded warning. BMS's presentation of risk information lacks prominence compared to the benefit claims and minimizes the potential serious risks associated with Tequin therapy.

BMS should immediately cease dissemination of these and similar claims and presentations in all promotional materials for Tequin. BMS should submit in writing, on or before April 24, 2000, a description of the steps that will be taken to comply with the above request.

BMS should direct its response to the undersigned by facsimile at (301) 594-6771, or by written communication at the Division of Drug Marketing, Advertising, and Communications, HFD-42; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857. We remind you that only written communications are considered official.

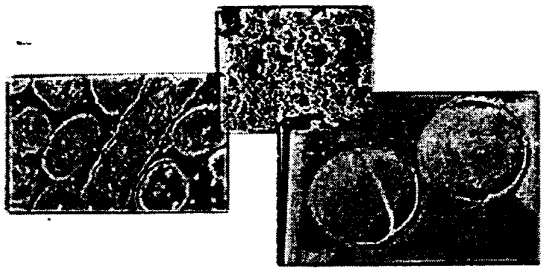
In all future correspondence regarding this matter, please refer to MACMIS ID# 8782 and NDA 21-061/062.

Sincerely,

/S/

Jean-Ah Choi, Pharm.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications

Tequin
gatifloxacin



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A new antibiotic from Bristol-Myers Squibb

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"Tequin represents the newest antibiotic to emerge from Bristol-Myers Squibb and offers physicians a new type of quinolone antibiotic to treat respiratory tract infections."

Press Room

Press release (3/15/00) | Press Release (1/15/00) | Noticias en Español (1/15/00)
Tequin Product Shot | Tequin VNR Quicktme | Tequin VNR Realtime

Bristol-Myers Squibb Receives FDA Approval For Tequin, A New Type Of Quinolone Antibiotic

New, Advanced Quinolone Antibiotic is Designed to Treat Indications Including Respiratory Tract Infections

PRINCETON, NEW JERSEY, January 5, 2000 -- Bristol-Myers Squibb Company (NYSE: BMY) has announced that *Tequin* ™ (gatifloxacin), a new type of quinolone antibiotic, has been approved by the U.S. Food and Drug Administration for indications including the treatment of community-acquired respiratory tract infections (RTIs). *Tequin* was designed with a unique 8-methoxy structure that appears to enhance bactericidal action and decrease the rate of the development of resistance of gram-positive bacteria. *Tequin* is the first and only antibiotic of this type available in bioequivalent 400 mg oral and IV formulations.

"The major challenge for physicians treating common respiratory infections is finding an antibiotic that eradicates the major organisms and is safe and easy for patients to take," commented Michael S. Niederman, M.D., chief, Division of Pulmonary and Critical Care Medicine, and acting chairman, Department of Medicine, Winthrop-University Hospital, Mineola, New York. "*Tequin* shows greater than 90 percent clinical cure and eradication rates of the pathogens most responsible for RTIs, particularly *Streptococcus pneumoniae* , which accounts for more than 40 percent of community respiratory infections in the U.S."

Tequin has been shown in clinical trials to provide excellent efficacy and tolerability. *Tequin* is effective in the treatment of patients with acute exacerbation of chronic bronchitis, acute sinusitis and community-acquired pneumonia caused by indicated susceptible strains of gram-positive and gram-negative bacteria that include *S. pneumoniae* , *Haemophilus influenzae* , *Moraxella catarrhalis* , *Mycoplasma pneumoniae* , *Chlamydia pneumoniae* and *Legionella pneumoniae* .

Tequin has produced an overall clinical success rate of ≥ 90 percent in acute exacerbation of chronic bronchitis, 96 percent in acute sinusitis and ≥ 97 percent in community-acquired pneumonia.

The incidence of respiratory tract infections, such as bronchitis, sinusitis and community-acquired pneumonia, has increased almost 50 percent in the past 10 years in the U.S. -- to approximately 125 million cases per year. The rise in RTIs has driven the development of newer antibiotics, such as macrolides and fluoroquinolones. The mechanism of action of fluoroquinolones including *Tequin* is different from that of penicillins, cephalosporins, aminoglycosides, macrolides and tetracyclines. Therefore, fluoroquinolones may be active against pathogens that are resistant to these other antibiotics. There was no cross-resistance between *Tequin* and these other drugs. In clinical trials, the *in vitro* activity of *Tequin* against important respiratory

tract pathogens was greater than 99 percent.

"*Tequin* represents the newest antibiotic to emerge from Bristol-Myers Squibb and offers physicians a new type of quinolone antibiotic to treat RTIs," commented Rick Lane, president, Worldwide Medicines Group, Bristol-Myers Squibb. "Its development is consistent with our heritage and longstanding commitment to infectious disease, as well as our company's mission of extending and enhancing human life."

Tequin is primarily excreted through the kidneys and less than 1 percent is metabolized by the liver. To date, *Tequin* has been administered worldwide to over 10,000 adult patients in clinical trials. It has been found to be a safe and well-tolerated treatment at 500 study sites in 15 international clinical trials. In a clinical study (n=48), *Tequin* demonstrated a lower potential for producing delayed photosensitivity skin reactions than ciprofloxacin or lomefloxacin, and was comparable to placebo in causing these same reactions.

Tequin is dosed 400 mg once daily for all indications. The availability of *Tequin* in bioequivalent 400 mg oral and IV formulations facilitates an easy transition for patients who begin treatment in the hospital and continue on oral therapy at home.

The most common side effects associated with *Tequin* in clinical trials were gastrointestinal. Adverse reactions considered to be drug related and occurring in $\geq$ 3 percent of patients were: nausea (8 percent), vaginitis (6 percent), diarrhea (4 percent), headache (3 percent) and dizziness (3 percent). *Tequin* should not be administered within four hours before or after administration of an antacid or a mineral supplement, such as iron or calcium.

The safety and efficacy of *Tequin* in children, adolescents (under 18), pregnant women and nursing mothers have not been established. *Tequin* is contraindicated in persons with a history of hypersensitivity to gatifloxacin or any member of the quinolone class of antimicrobial agents. As with other quinolones, *Tequin* should be used with caution in patients with known or suspected central nervous system disorders or patients who have a predisposition to seizures. *Tequin* may have the potential to prolong the QTc interval of the electrocardiogram in some patients, and, due to limited clinical experience, *Tequin* should be avoided in patients with known prolongation of the QTc interval, patients with uncorrected hypokalemia and patients receiving Class IA (e.g., quinidine, procainamide) or Class III (e.g., amiodarone, sotalol) antiarrhythmic agents. *Tequin* should be used with caution when given together with drugs that may prolong the QTc interval (e.g., cisapride, erythromycin, antipsychotics, tricyclic antidepressants), and in patients with ongoing proarrhythmic conditions (e.g., clinically significant bradycardia or acute myocardial ischemia).

Tequin was licensed by Bristol-Myers Squibb from Kyorin Pharmaceutical Company Ltd. in September 1996, for development and marketing in the U.S., Canada, Brazil, Mexico, Argentina, Australia, and certain other countries.

Bristol-Myers Squibb is a diversified worldwide health and personal care company whose principal businesses are pharmaceuticals, consumer products, nutritionals, and medical devices. It is a leading

maker of innovative therapies for cardiovascular, metabolic and infectious diseases, central nervous system and dermatological disorders, and cancer. The company is also a leader in consumer medicines, orthopaedic devices, ostomy care, wound management, nutritional supplements, infant formulas, and hair and skin care products.

For full *Tequin* prescribing information, click here.

For more information, contact: Mark Short, 609-897-2742 or mark.short@bms.com, or Patricia Doykos Duquette, Ph.D., 609-897-3077 or patricia.duquette@bms.com

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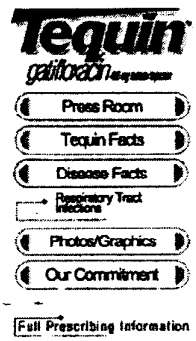

Tequin delivers strong clinical efficacy.

Tequin Facts

Tequin (gatifloxacin)

8-Methoxy Side Chain Fact Sheet

Tequin (Gatifloxacin)

- *Tequin* ™ (gatifloxacin), a new broad-spectrum 8-methoxy fluoroquinolone antibiotic, has recently been approved by the U.S. Food and Drug Administration for the safe and effective treatment of approved indications including community-acquired respiratory tract infections.
- *Tequin* has been shown in clinical trials to provide strong clinical efficacy with an excellent tolerability profile in the treatment of patients with acute exacerbation of chronic bronchitis, acute sinusitis and community-acquired pneumonia due to susceptible strains of indicated bacteria.
- *Tequin* delivers strong clinical efficacy
    - 96 percent clinical success rate in sinusitis
    - ≥ 90 percent clinical success rate in bronchitis (ABECB)
    - ≥ 97 percent clinical success rate in community-acquired pneumonia (CAP
- It appears that the C-8-methoxy segment of the *Tequin* chemical structure contributes to enhanced activity and lower selection of resistant mutants of gram-positive bacteria.
- The mechanism of action of fluoroquinolones including *Tequin* is different from that of penicillins, cephalosporins, aminoglycosides, macrolides and tetracyclines. Therefore, fluoroquinolones may be active against pathogens that are resistant to these other antibiotics. There is no cross-resistance between *Tequin* and these other drugs.
- The recommended dose for *Tequin* is 400 mg once daily, for all indications. *Tequin* is available in bioequivalent oral or IV forms.
- *Tequin* is primarily excreted through the kidneys and less than 1 percent is metabolized by the liver.
- To date, *Tequin* has been administered worldwide to over 10,000 adult patients in clinical trials. It has been found to be a safe and well-tolerated treatment at 500 study sites in 15 international clinical trials.
- In a clinical study (n=48), *Tequin* demonstrated a lower potential for producing delayed photosensitivity skin reactions than ciprofloxacin or lomefloxacin, and was comparable to

placebo in causing these same reactions.

- The most common side effects associated with *Tequin* in clinical trials were gastrointestinal. Adverse reactions considered to be drug related and occurring in ≥ 3 percent of patients were: nausea (8 percent), vaginitis (6 percent), diarrhea (4 percent), headache (3 percent) and dizziness (3 percent).

- *Tequin* should not be administered within four hours of administration of an antacid or a mineral supplement, such as iron or calcium.

- The safety and efficacy of *Tequin* in children, adolescents (under 18), pregnant women and nursing mothers have not been established. *Tequin* is contraindicated in persons with a history of hypersensitivity to gatifloxacin or any member of the quinolone class of antimicrobial agents. As with other quinolones, *Tequin* should be used with caution in patients with known or suspected central nervous system disorders or patients who have a predisposition to seizures. *Tequin* may have the potential to prolong the QTc interval of the electrocardiogram in some patients, and, due to limited clinical experience, *Tequin* should be avoided in patients with known prolongation of the QTc interval, patients with uncorrected hypokalemia and patients receiving Class IA (e.g., quinidine, procainamide) or Class III (e.g., amiodarone, sotalol) antiarrhythmic agents. *Tequin* should be used with caution when given together with drugs that may prolong the QTc interval (e.g., cisapride, erythromycin, antipsychotics, tricyclic antidepressants), and in patients with ongoing proarrhythmic conditions (e.g., clinically significant bradycardia or acute myocardial ischemia).

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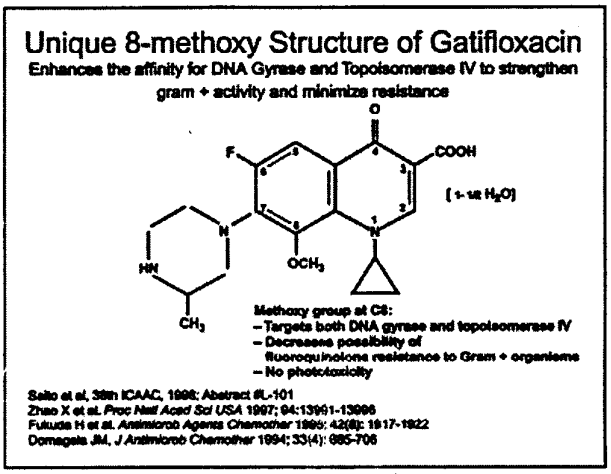
Tequin is the only 8-methoxy antibiotic on the market available in bioequivalent oral and IV formulations.

Tequin Facts

Tequin (gatifloxacin)

8-Methoxy Side Chain Fact Sheet

8-Methoxy Side Chain Fact Sheet



for full color version

- *Tequin* ™ (gatifloxacin) is an 8-methoxy fluoroquinolone with *in vitro* activity against a wide range of gram-positive and gram-negative organisms.
- It appears that the C-8-methoxy segment of the *Tequin* chemical structure contributes to enhanced activity and lower selection of resistant mutants of gram-positive bacteria.
- The chemical structure of *Tequin* requires two mutations for bacteria to develop resistance. *Tequin* kills bacteria by inhibiting two enzymes: DNA gyrase and topoisomerase IV. For bacteria to develop resistance against *Tequin*, they must develop mutations in both enzymes. Thus, the chance of susceptible bacteria to develop resistance to *Tequin* is extremely low.
- Bacteria need DNA gyrase to replicate, transcribe and repair their DNA. Activity against DNA gyrase accounts for much of the strength of *Tequin* against gram-negative bacteria.
- For cell division, bacteria need topoisomerase IV. Activity against topoisomerase IV accounts for much of the increased activity of *Tequin* against gram-positive pathogens.
- *Tequin* was developed to cover common respiratory pathogens including *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Moraxella catarrhalis*, as well as atypical bacteria. *Tequin*

has been approved by the U.S. Food and Drug Administration (FDA) for the safe and effective treatment of approved indications which include community-acquired respiratory tract infections caused by indicated susceptible strains of gram-positive and gram-negative bacteria.

- *Tequin* (gatifloxacin) is the only 8-methoxy antibiotic on the market available in bioequivalent oral and IV formulations.
- *Tequin* is the only 8-methoxy antibiotic on the market that is eliminated primarily by renal excretion. Less than one percent of *Tequin* is metabolized by the liver.
- To date, *Tequin* has been administered worldwide to over 10,000 adult patients in clinical trials. It has been found to be a safe and well-tolerated treatment in 15 international clinical trials at 500 study sites. In a clinical study (n=48), *Tequin* demonstrated a lower potential for producing delayed photosensitivity skin reactions than ciprofloxacin or lomefloxacin, and was comparable to placebo in causing these same reactions.
- The most common side effects associated with *Tequin* in clinical trials were gastrointestinal. Adverse reactions considered to be drug related and occurring in greater than three percent of patients were: nausea (8 percent), vaginitis (6 percent), diarrhea (4 percent), headache (3 percent) and dizziness (3 percent).
- *Tequin* should not be administered within four hours of administration of an antacid or a mineral supplement, such as iron or calcium.
- The safety and efficacy of *Tequin* in children, adolescents (under 18), pregnant women and nursing mothers have not been established. *Tequin* is contraindicated in persons with a history of hypersensitivity to gatifloxacin or any member of the quinolone class of antimicrobial agents. As with other quinolones, *Tequin* should be used with caution in patients with known or suspected central nervous system disorders or patients who have a predisposition to seizures. *Tequin* may have the potential to prolong the QTc interval of the electrocardiogram in some patients, and, due to limited clinical experience, *Tequin* should be avoided in patients with known prolongation of the QTc interval, patients with uncorrected hypokalemia and patients receiving Class IA (e.g., quinidine, procainamide) or Class III (e.g., amiodarone, sotalol) antiarrhythmic agents. *Tequin* should be used with caution when given together with drugs that may prolong the QTc interval (e.g., cisapride, erythromycin, antipsychotics, tricyclic antidepressants), and in patients with ongoing proarrhythmic conditions (e.g., clinically significant bradycardia or acute myocardial ischemia).

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Disease Facts

Respiratory Tract Infections (RTIs) Treatment

- Acute Exacerbation Of Chronic Bronchitis (AEC)
- Acute Sinusitis
- Community-Acquired Pneumonia (CAP)

Respiratory tract infections are the most commonly treated infections in the U.S. and Latin America.

Respiratory Tract Infections: Challenges Of Coverage And Safety

Respiratory tract infections (RTIs) are the most commonly treated infections in the United States, accounting for 50 percent of all oral antibiotics prescribed in this country.[1] Upper RTIs (e.g., sinusitis) and lower RTIs (e.g., chronic bronchitis and community-acquired pneumonia, an infection occurring in a non-hospitalized person) account for 21 percent and 15 percent of prescriptions, respectively. Sinusitis is the most frequently reported chronic condition, affecting more than 10 percent of the U.S. population. Respiratory tract infections are also the most commonly treated infections in Latin America, accounting for 45 percent of all oral antibiotics prescribed in that region.[2]

Selecting Treatment To effectively treat RTIs, clinicians must be aware of key pathogens in order to select the antibiotic that covers the causative pathogen. The Infectious Diseases Society of America (IDSA) reports that *Streptococcus pneumoniae* is the most commonly reported pathogen of community-acquired pneumonia, and one of the most common causes of RTIs.[3] *S. pneumoniae* is a leading cause of morbidity and mortality in the United States. It is responsible for more than 500,000 cases of pneumonia per year and for approximately 40,000 deaths annually due to pneumonia, bacteremia and meningitis.[4]

According to a meta-analysis of community-acquired pneumonia that included 33,148 patients, *Haemophilus influenzae* was the second most commonly reported pathogen after *S. pneumoniae*, accounting for 12 percent of reported cases.[5]

Among the agents commonly prescribed to treat RTIs are: penicillin, cephalosporins, macrolides and, recently, quinolones.

The Early Treatments

From the original penicillin dating to 1928, which is active against some gram-positive bacteria, a number of semisynthetic penicillins have been developed to cover a broad spectrum of gram-positive and gram-negative organisms as well as to overcome the inactivation of penicillin by penicillinase, an enzyme produced by *Staphylococcus aureus.*

Cephalosporins

The cephalosporins are a class of antibiotics with the same mode of

action as the penicillins. They also share a component of penicillin's chemical structure, known as the beta-lactam ring. For this reason, the cephalosporins and the penicillins are sometimes referred to collectively as beta-lactam antibiotics. The cephalosporins were developed in part to overcome the emerging penicillin resistance associated with *S. aureus*. However, their evolution has followed a similar pattern to the penicillins, with significant resistance patterns developing with the advent of each new generation.

Macrolides

The macrolides -- erythromycin, clarithromycin and azithromycin -- are active against many gram-positive and gram-negative cocci and atypical organisms; the newer agents are also active against *H. influenzae* and *Moraxella catarrhalis*. The activity of these agents may be bacteriostatic or bactericidal depending on factors such as the drug concentration and growth phase of the pathogen.

Early Quinolones

The bacterial spectrum of the original quinolone, nalidixic acid (1962), was limited to gram-negative organisms. Unfortunately, resistance to nalidixic acid developed rapidly. The development of the early fluoroquinolones, such as ciprofloxacin, provided potency against gram-negative organisms and expanded the antibacterial spectrum of these agents to include some gram-positive bacteria and atypical organisms. To date, the newer fluoroquinolones have been much less susceptible to bacterial resistance than nalidixic acid.

The Advanced And Newer Quinolones

The use of quinolones has risen in recent years.[7] The most marked increase in use has been for the treatment of RTIs. With the extended coverage of newer fluoroquinolones against common respiratory pathogens, including *S. pneumoniae* , beta lactamase-producing *H. influenzae* and *Moraxella catarrhalis* and atypical organisms, the use of this class is expected to continue increasing and is, in fact, recommended in various treatment guidelines.[7] Currently available advanced quinolones can vary significantly with respect to clinical efficacy, bacteriologic eradication rates and safety.[8]

For these reasons, infectious disease experts and leading organizations such as the World Health Organization (in its 1999 Infectious Disease Report) continue to call for the development of newer anti-infectives that provide greater reliability and assurance in the treatment of RTIs. In particular, agents need to provide the right coverage and optimal activity against primary RTI pathogens, including *S. pneumoniae* , *H. influenzae* , *M. catarrhalis* and atypical pathogens, with a favorable safety and tolerability profile.

Tequin (gatifloxacin) -- A New Type Of Advanced Generation Fluoroquinolone

Tequin ™ (gatifloxacin) is a new broad-spectrum 8-methoxy fluoroquinolone antibiotic that has recently been approved by the U.S. Food and Drug Administration for the safe and effective treatment of approved indications including community-acquired respiratory tract

infections. *Tequin* has been shown in clinical trials to provide strong clinical efficacy with an excellent tolerability profile in the treatment of patients with acute exacerbation of chronic bronchitis, acute sinusitis and community-acquired pneumonia due to susceptible strains of indicated bacteria.

Tequin delivers strong clinical efficacy, with 96 percent clinical success rate in sinusitis, ≥ 90 percent clinical success rate in bronchitis (ABECB) and ≥ 97 percent clinical success rate in community-acquired pneumonia (CAP).

It appears that the C-8-methoxy segment of the *Tequin* chemical structure contributes to enhanced activity and lower selection of resistant mutants of gram-positive bacteria. The mechanism of action of fluoroquinolones including *Tequin* is different from that of penicillins, cephalosporins, aminoglycosides, macrolides and tetracyclines. Therefore, fluoroquinolones may be active against pathogens that are resistant to these other antibiotics. There is no cross-resistance between *Tequin* and these other drugs.

The recommended dose for *Tequin* is 400 mg once daily, for all indications. *Tequin* is available in bioequivalent oral or IV forms.

Tequin is primarily excreted through the kidneys and less than one percent is metabolized by the liver. To date, *Tequin* has been administered to over 10,000 patients worldwide. *Tequin* has been found to be safe and well-tolerated at 500 study sites in 15 international clinical trials. In a clinical study (n=48), *Tequin* demonstrated a lower potential for producing delayed photosensitivity skin reactions than ciprofloxacin or lomefloxacin, and was comparable to placebo in causing these same reactions.

The most common side effects associated with *Tequin* in clinical trials were gastrointestinal. Adverse reactions considered to be drug related and occurring in >3 percent of patients were: nausea (8 percent), vaginitis (6 percent), diarrhea (4 percent), headache (3 percent) and dizziness (3 percent).

Tequin should not be administered within four hours of administration of an antacid or a mineral supplement, such as iron or calcium.

The safety and efficacy of *Tequin* in children, adolescents (under 18), pregnant women and nursing mothers have not been established. *Tequin* is contraindicated in persons with a history of hypersensitivity to gatifloxacin or any member of the quinolone class of antimicrobial agents. As with other quinolones, *Tequin* should be used with caution in patients with known or suspected central nervous system disorders or patients who have a predisposition to seizures. *Tequin* may have the potential to prolong the QTc interval of the electrocardiogram in some patients, and, due to limited clinical experience, *Tequin* should be avoided in patients with known prolongation of the QTc interval, patients with uncorrected hypokalemia and patients receiving Class IA (e.g., quinidine, procainamide) or Class III (e.g., amiodarone, sotalol) antiarrhythmic agents. *Tequin* should be used with caution when given together with drugs that may prolong the QTc interval (e.g., cisapride, erythromycin, antipsychotics, tricyclic antidepressants), and in

patients with ongoing proarrhythmic conditions (e.g., clinically significant bradycardia or acute myocardial ischemia).

For Full Prescribing Information

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