

Reduced serum globulin and protein levels were observed in animals treated with other quinolones. In one ofloxacin study, minor decreases in serum globulin and protein levels were noted in female cynomolgus monkeys dosed orally with 40 mg/kg ofloxacin daily for one year. These changes, however, were considered to be within normal limits for monkeys.

Crystalluria and ocular toxicity were not observed in any animals treated with ofloxacin.

FLOXIN[®] is a trademark of ORTHO-McNEIL PHARMACEUTICAL, INC.

U.S. Patent No. 4,382,892

REFERENCES

1. National Committee for Clinical Laboratory Standards. Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically - Fourth Edition. Approved Standard NCCLS Document M7-A4, Vol. 17, No. 2, NCCLS, Wayne, PA, January, 1997.
 2. National Committee for Clinical Laboratory Standards. Performance Standards for Antimicrobial Disk Susceptibility Tests - Sixth Edition. Approved Standard NCCLS Document M2-A6, Vol. 17, No. 1, NCCLS, Wayne, PA, January 1997.
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Patient Information About:

FLOXIN[®] (ofloxacin) Tablets

200 mg Tablets, 300 mg Tablets and 400 mg Tablets

This leaflet contains important information about FLOXIN[®] (ofloxacin), and should be read completely before you begin treatment. This leaflet does not take the place of discussions with your doctor or health care professional about your medical condition or your treatment. This leaflet does not list all benefits and risks of FLOXIN[®]. The medicine described here can be prescribed only by a licensed health care professional. If you have any questions about FLOXIN[®] talk to your health care professional. Only your health care professional can determine if FLOXIN[®] is right for you.

What is FLOXIN[®]?

FLOXIN[®] is a quinolone antibiotic used to treat lung, skin, and urinary tract infections caused by certain germs called bacteria. FLOXIN[®] kills many of the types of bacteria that can infect the lungs, skin, and urinary tract and 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. FLOXIN[®], like other antibiotics, does not kill viruses.

You should contact your health care professional if you think that your condition is not improving while taking FLOXIN[®]. FLOXIN[®] Tablets are light yellow for the 200 mg tablet, white colored for the 300 mg tablet, or pale gold for the 400 mg tablet.

How and when should I take FLOXIN[®]?

FLOXIN[®] should be taken once as a single dose, or twice a day for 3 days to 6 weeks depending on the prescription. FLOXIN[®] Tablets should be swallowed and may be taken with or without food. Try to take the tablets at the same times each day and drink fluids liberally.

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 FLOXIN[®] even if you missed a dose by mistake. You should not take a double dose.

Who should not take FLOXIN[®]?

You should not take FLOXIN[®] if you have ever had a severe allergic reaction to any of the group of antibiotics known as “quinolones” such as ciprofloxacin. Serious and occasionally fatal allergic reactions have been reported in patients receiving therapy with quinolones, including FLOXIN[®].

If you are pregnant or are planning to become pregnant while taking FLOXIN[®], talk to your health care professional before taking this medication. FLOXIN[®] is not recommended for use during pregnancy or nursing, as the effects on the unborn child or nursing infant are unknown.

FLOXIN[®] is not recommended for children.

What are the possible side effects of FLOXIN[®]?

FLOXIN[®] is generally well tolerated. The most common side effects caused by FLOXIN[®], which are usually mild, include nausea, sleeplessness, headache, dizziness, diarrhea, vomiting, rash, itching, external genital itching in women, vaginitis, and impaired taste.

You should be careful about driving or operating machinery until you are sure FLOXIN[®] is not causing dizziness.

Allergic reactions have been reported in patients receiving quinolones including FLOXIN[®], even after just one dose. If you develop hives, skin rash or other symptoms of an allergic reaction, you should stop taking this medication and call your health care professional.

Pain, swelling, and tears of Achilles, shoulder, or hand tendons have been reported in patients receiving fluoroquinolones, including FLOXIN[®]. The risk for tendon effects is higher if you are over 65 years old, and especially if you are taking corticosteroids. If you develop pain, swelling, or rupture of a tendon you should stop taking FLOXIN[®], avoid exercise and strenuous use of the affected area, and contact your health care provider.

Some quinolone antibiotics have been associated with the development of phototoxicity (“sunburns” and “blistering sunburns”) following exposure to sunlight or other sources of ultraviolet light such as artificial ultraviolet light used in tanning salons. FLOXIN[®] has been infrequently associated with phototoxicity. You should avoid excessive exposure to sunlight or artificial ultraviolet light while you are taking FLOXIN[®].

If you have diabetes and you develop a hypoglycemic reaction while on FLOXIN[®], you should stop taking FLOXIN[®] and call your health care professional.

Convulsions have been reported in patients receiving quinolone antibiotics including FLOXIN[®]. If you have experienced convulsions in the past, be sure to let your physician know that you have a history of convulsions.

Quinolones, including FLOXIN[®], may also cause central nervous system stimulation which may lead to tremors, restlessness, anxiety, lightheadedness, confusion, hallucinations, paranoia, depression, nightmares, insomnia, and rarely, suicidal thoughts or acts.

Diarrhea that usually ends after treatment is a common problem caused by antibiotics. A more serious form of diarrhea can occur during or up to 2 months after the use of antibiotics. This has been reported with all antibiotics including with FLOXIN[®]. If you develop a watery and bloody stool with or without stomach cramps and fever, contact your physician as soon as possible.

In a few people, FLOXIN[®], like some other antibiotics, may produce a small effect on the heart that is seen on an electrocardiogram test. The rare heart problem is called

QT prolongation and can cause an abnormal heartbeat and can be very dangerous. The chances of this event are increased in those with a family history of prolonged QT interval, low potassium (hypokalemia), and who are taking drugs to control heart rhythm, called class IA (quinidine, procainamide) or class III (amiodarone, sotalol) antiarrhythmic agents. You should call your healthcare provider right away if you have any prolonged heart palpitations (a change in the way your heart beats) or a loss of consciousness (fainting spells).

If you notice any side effects not mentioned in this leaflet or you have concerns about the side effects you are experiencing, please inform your health care professional.

For more complete information regarding ofloxacin, please refer to the full prescribing information, which may be obtained from your health care professional, pharmacist, or the Physicians Desk Reference (PDR).

What about other medicines I am taking?

Taking warfarin (Coumadin[®]) and FLOXIN[®] together can further predispose you to the development of bleeding problems. If you take warfarin, be sure to tell your health care professional.

Many antacids and multivitamins may interfere with the absorption of FLOXIN[®] and may prevent it from working properly. You should take FLOXIN[®] either 2 hours before or 2 hours after taking these products.

It is important to let your health care professional know all of the medicines you are using.

Other information

Take your dose of FLOXIN[®] twice a day or once as a single dose depending on the prescription.

Complete the course of medication even if you are feeling better.

Keep this medication out of the reach of children.

Some quinolones, including ofloxacin, may produce false-positive urine screening results for opiates using commercially available immunoassay kits. Confirmation of positive opiate screens by more specific methods may be necessary.

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Rx Only

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