

PATIENT INFORMATION ABOUT PROQUIN XR

PROQUIN[®] XR

(prōkwīn)

(ciprofloxacin hydrochloride)

Extended-Release Tablets, 500 mg

This leaflet contains important information about Proquin XR (ciprofloxacin hydrochloride) extended-release tablets and should be read before you begin treatment. This leaflet does not replace talking with your doctor about your medical condition or your treatment. This leaflet does not list all benefits and risks of Proquin XR. Proquin XR can be prescribed only by a doctor. If you have any questions about Proquin XR, talk to your doctor. Only your doctor can tell you if Proquin XR is right for you.

2.1.10 What is Proquin XR?

Proquin XR is an antibiotic in the class known as “quinolones” that is used to treat adults with simple (uncomplicated) urinary tract infections (also known as “bladder infections”) caused by bacteria. It is not known if Proquin XR will treat infections other than bladder infections. Proquin XR, like all other antibiotics, does not kill viruses.

You should contact your doctor if you do not feel better or if you develop fever and back pain while or after taking Proquin XR.

Proquin XR tablets are blue and contain 500 mg of active drug.

2.1.11 How should I take Proquin XR?

- Proquin XR should be taken once a day for 3 days shortly after a main meal of the day, preferably the evening meal. Proquin XR does not work as well if you take it without a meal. You should try to take Proquin XR at about the same time each day.
- Take Proquin XR for all 3 days, even if you are feeling better. If you stop taking Proquin XR before all 3 doses, Proquin XR may not cure your bladder infection.
- **Do not split, crush, or chew Proquin XR tablets.** Proquin XR tablets must be swallowed whole. Tell your doctor if you cannot swallow tablets whole. Your doctor will prescribe a different medicine for you.
- Do not take more than one Proquin XR tablet a day, even if you miss a dose.
- Do not take Proquin XR at the same time that you drink milk or juices with added calcium, unless you drink them with a main meal.
- Many antacids and multivitamins may interfere with the absorption of Proquin XR if taken at the same time. Take Proquin XR at least 4 hours before or 2 hours after antacids that contain magnesium or aluminum. Proquin XR should also be taken at least 4 hours before or 2 hours after sucralfate, VIDEX[®] (didanosine) chewable buffered tablets or pediatric powder, iron, calcium, and vitamins that contain zinc.

2.1.12 Who should not take Proquin XR?

Do not take Proquin XR if you are allergic to or have ever had a severe reaction to ciprofloxacin or to any other "quinolone" antibiotics.

Proquin XR is not recommended for use during pregnancy or nursing, as the effects on the unborn child or nursing infant are unknown. If you are pregnant or planning to become pregnant while taking Proquin XR, talk to your doctor before taking this medication.

Proquin XR is not recommended for children.

2.1.13 What should I tell my doctor before taking Proquin XR?

Tell your doctor about all of your medical conditions, including if you have or ever had seizures (epilepsy), asthma, or liver or kidney problems.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins and herbal supplements. Proquin XR and certain other medicines can affect each other. You may have to adjust the times you take certain other medicines, vitamins, and herbal supplements. Especially, tell your doctor if you take: theophylline, VIDEX[®] (didanosine) chewable buffered tablets or pediatric powder; warfarin (Coumadin[®]); glyburide (Glucovance[®], Micronase[®], DiaBeta[®]); phenytoin (Dilantin[®]); sucralfate (Carafate[®]); or antacids or vitamins that contain magnesium, calcium, aluminum, iron, or zinc.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist.

2.1.14 What are the possible side effects of Proquin XR?

Proquin XR is generally well tolerated. The most common side effects with Proquin XR include vaginal yeast infection and headache. Less common side effects include nausea, diarrhea, dizziness, and abdominal pain.

You should be careful about driving or operating machinery until you are sure the Proquin XR is not causing dizziness or lightheadedness.

Rare cases of allergic reactions have been reported in patients receiving quinolones, including ciprofloxacin, even after just one dose. Stop taking Proquin XR and call your doctor or get emergency medical attention right away if you develop a rash, hives, swelling of your face or throat, or have trouble breathing.

Sun sensitivity (photosensitivity) which can appear as skin eruption or severe sunburn, can occur in some patients taking quinolone antibiotics after exposure to sunlight or artificial ultraviolet light (UV) (e.g. tanning beds). Proquin XR has been infrequently associated with photosensitivity. Avoid excessive exposure to sunlight or artificial UV light while taking Proquin XR. Use a sunscreen and wear protective clothing if out in the sun. If photosensitivity develops, contact your physician.

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

Convulsions have been reported in patients receiving quinolone antibiotics including ciprofloxacin. Tell your doctor if you have experienced convulsions in the past. Quinolones, including ciprofloxacin, have been rarely associated with other central nervous system events including confusion, tremors, hallucinations, and depression. Stop taking Proquin XR and call your doctor right away if you get any of these symptoms.

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 Proquin XR. If you develop a watery and bloody stool with or without stomach cramps and fever, contact your physician as soon as possible.

These are not all the side effects with Proquin XR. For more information, ask your doctor or pharmacist.

2.1.15 How should I store Proquin XR?

- Store Proquin XR at room temperature, 59° to 86°F (15° to 30°C).
- Keep Proquin XR and all medicines out of the reach of children.

2.1.16 What are the ingredients in Proquin XR?

Active Ingredient: ciprofloxacin hydrochloride

Inactive Ingredients: film coating, magnesium stearate, polyethylene oxide, and povidone.

2.1.17 General information about Proquin XR

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use Proquin XR for a condition for which it was not prescribed. Do not give Proquin XR to other people, even if they have the same symptoms you have. It may harm them.

Keep this medication out of the reach of children.

This leaflet summarizes the most important information about Proquin XR. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about Proquin XR that is written for health care professionals. Further information is also provided at:

Medical Inquiries: 1-866-458-6389 and www.proquinxr.com

Rx Only

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Proquin® XR is manufactured for:

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