

17.12 Use of Proquin XR Sample Pack

Advise the patient that the sample pack contains only one dose for the first day of treatment with Proquin[®] XR. Complete treatment requires 3 doses. The patient must fill a prescription for the remaining two doses.

17.13 Human Milk Feeding

Advise women to avoid feeding their infants with their milk during treatment with Proquin XR. Women should either discontinue feeding or pump and discard their milk during treatment and for 24 hours after the last dose [see *Use in Specific Populations (8.3)*].

17.14 Antibacterial Resistance

Antibacterial drugs including Proquin XR should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When Proquin XR is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by Proquin XR or other antibacterial drugs in the future [see *Warnings and Precautions (5.10)*].

PROQUIN[®] XR (pro-kwin) (Ciprofloxacin) Extended-Release Tablets

Read the Medication Guide that comes with Proquin[®] XR before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about Proquin[®] XR?

Proquin[®] XR belongs to a class of antibiotics called fluoroquinolones. Proquin[®] XR can cause side effects that may be serious or even cause death. If you get any of the following serious side effects, get medical help right away, and talk with your healthcare provider about whether you should continue to take Proquin[®] XR.

Tendon rupture or swelling of the tendon (tendonitis)

- Tendons are the tough cords of tissue that connects muscles to bones.
- Pain, swelling, inflammation of tendons including the back of the ankle (Achilles), shoulder, hand, or other tendon sites can happen in people of all ages who take fluoroquinolone antibiotics, including Proquin[®] XR. The risk of getting tendon problems is higher if you:
 - are over 60 years of age
 - are taking steroids (corticosteroids)
 - have had a kidney, heart or lung transplant

- Swelling of the tendon (tendonitis) and tendon rupture (breakage) have also happened in patients who take fluoroquinolones who do not have the above risk factors.
- Other reasons for tendon ruptures include:
 - physical activity or exercise
 - kidney failure
 - tendon problems in the past, such as in people with rheumatoid arthritis (RA).
- Call your healthcare provider right away at the first sign of tendon pain, swelling, or inflammation. Stop taking Proquin[®] XR until tendinitis or tendon rupture has been ruled out by your healthcare provider. Avoid exercise and using the affected area. The most common area of pain and swelling is the Achilles tendon at the back of your ankle. This can also happen with other tendons. Talk to your healthcare provider about the risk of tendon rupture with continued use of Proquin[®] XR. You may need a different antibiotic that is not a fluoroquinolone to treat your infection.
- Tendon rupture can happen while you are taking or after you have finished taking Proquin[®] XR. Tendon ruptures have happened up to several months after patients have finished taking their fluoroquinolone.
- Get medical help right away if you get any of the following signs or symptoms of a tendon rupture:
 - hear or feel a snap or pop in a tendon area
 - bruising right after an incident in a tendon area
 - unable to move the affected area or bear weight
- **Worsening of myasthenia gravis (a disease which causes muscle weakness).** Fluoroquinolones like **Proquin XR** may cause worsening of myasthenia gravis symptoms, including muscle weakness and breathing problems. Call your healthcare provider right away if you have any worsening muscle weakness or breathing problems.

See the section “**What are the possible side effects of Proquin[®] XR?**” for more information about side effects.

What is Proquin[®] XR?

Proquin[®] XR is a fluoroquinolone antibiotic medicine used to treat simple bladder infections caused by certain germs called bacteria.

It is not known if Proquin[®] XR is safe and works in treating any infections other than simple bladder infections.

It is also not known if Proquin[®] XR is safe and works in children under 18 years of age.

Children have a higher chance of getting bone and joint (musculoskeletal) problems while taking fluoroquinolone antibiotic medicines.

Sometimes infections are caused by viruses rather than by bacteria. Examples include viral infections in the sinuses and lungs, such as the common cold or flu. Antibiotics including Proquin[®] XR do not kill viruses.

Call your healthcare provider if you think your condition is not getting better while you are taking Proquin[®] XR.

Who should not take Proquin[®] XR?

Do not take Proquin[®] XR if you have ever had a severe allergic reaction to an antibiotic known as a fluoroquinolone, or are allergic to any of the ingredients in Proquin[®] XR. Ask your healthcare provider if you are not sure. See the complete list of ingredients in Proquin[®] XR at the end of this Medication Guide.

What should I tell my healthcare provider before taking Proquin[®] XR?

See “**What is the most important information I should know about Proquin[®] XR?**”

Before taking Proquin[®] XR, tell your healthcare provider if you:

- have tendon problems
- have a disease that causes muscle weakness (myasthenia gravis)
- have central nervous system problems (such as epilepsy)
- have or anyone in your family has an irregular heartbeat, especially a condition called “QT prolongation.”
- have a history of seizures
- have kidney problems
- have low blood potassium (hypokalemia)
- have rheumatoid arthritis (RA) or other history of joint problems
- have trouble swallowing pills
- are pregnant or planning to become pregnant. It is not known if Proquin[®] XR will harm your unborn child.
- are breast-feeding or planning to breast-feed. Proquin[®] XR can pass into your breast milk and may harm your baby. You and your healthcare provider should decide whether you will take Proquin[®] XR or breastfeed. You should not do both. See “What should I avoid while taking Proquin XR?”

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal and dietary supplements. Proquin[®] XR and certain other medicines can affect each other causing side effects. Especially tell your healthcare provider if you take:

- theophylline (Theo-24[®], Elixophyllin[®], Theochron[®], Uniphyl[®], Theolair[®]). Serious reactions, including death can happen in people who take Proquin XR and theophylline. Your healthcare provider may change your dose of theophylline and perform blood test to check your theophylline level if you take Proquin XR and theophylline.
- an NSAID (Non-Steroidal Anti-Inflammatory Drug). Many common medicines for pain relief are NSAIDs. Taking an NSAID while you take Proquin[®] XR or other

fluoroquinolones may increase your risk of central nervous system effects and seizures. See **“What are the possible side effects of Proquin® XR?”**

- a blood thinner (warfarin, Coumadin, Jantoven)
- glyburide (Micronase®, Glynase®, Diabeta®, Glucovance®)
- phenytoin (Fosphenytoin Sodium®, Cerebyx®, Dilantin-125®, Dilantin, Extended Phenytoin Sodium®, Prompt Phenytoin Sodium®, Phenytek®)
- products that contain caffeine
- a medicine to control your heart rate or rhythm (antiarrhythmics). See **“What are the possible side effects of Proquin® XR?”**
- an anti-psychotic medicine
- a tricyclic antidepressant
- a water pill (diuretic)
- a steroid medicine. Corticosteroids taken by mouth or by injection may increase the chance of tendon injury. See **“What is the most important information I should know about Proquin® XR?”**
- methotrexate (Trexall®)
- probenecid (Col-probenecid®)
- cyclosporine (Gengraf®, Sandimmune®, Neoral®)
- Certain medicines may keep Proquin® XR from working correctly. Take Proquin® XR at least 4 hours before or 2 hours after taking these products.
 - an antacid, multivitamin, or other product that contains magnesium, calcium, iron or zinc
 - sucralfate (Carafate)
 - didanosine (Videx®, Videx® EC)

Ask your healthcare provider if you are not sure if any of your medicines are listed above.

Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

What if I receive a sample of Proquin® XR from my healthcare provider?

This sample contains only 1 dose for the first day of treatment of Proquin® XR and is not a complete treatment. To treat your bladder infection, you must take all 3 daily doses of Proquin® XR. You must fill a prescription from your healthcare provider for the remaining two daily doses before your next scheduled dose. Take all of your doses as prescribed by your healthcare provider, even if you are feeling better after the first dose. If you stop taking Proquin® XR before all of your doses are complete, Proquin® XR may not cure your bladder infection. It is not known if Proquin® XR will treat infections other than bladder infections. See also **“How should I take Proquin® XR?”**

How should I take Proquin[®] XR?

- Take Proquin[®] XR exactly as prescribed by your healthcare provider.
- Proquin[®] XR should be taken by mouth one time each day for 3 days
- Take Proquin[®] XR with your main meal of the day, preferably the evening meal. Try to take Proquin[®] XR at about the same time each day.
- Swallow Proquin[®] XR tablets whole. Do not split, crush, or chew Proquin[®] XR tablets. Tell your healthcare provider if you can not swallow the tablets whole. Your healthcare provider will prescribe a different medicine for you.
- Drink plenty of fluids while taking Proquin[®] XR.
- 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.
- Proquin[®] XR does not work as well if you take it without a meal.
- Do not skip any doses, or stop taking Proquin[®] XR even if you begin to feel better, until you finish your prescribed treatment, unless:
 - you have tendon effects (see “**What is the most important information I should know about Proquin[®] XR?**”)
 - you have a serious allergic reaction (see “**What are the possible side effects of Proquin[®] XR?**”), or
 - your healthcare provider tells you to stop.

This will help make sure that all of the bacteria are killed and lower the chance that the bacteria will become resistant to Proquin[®] XR. If this happens, Proquin[®] XR and other antibiotic medicines may not work in the future.

- Tell your healthcare provider if you do not feel better or if you get fever and back pain, while you are taking Proquin[®] XR or after you finish taking it. This may mean that your infection has not been cured and you may need another antibiotic medicine to treat your infection.
- If you miss a dose of Proquin[®] XR, take it as soon as you remember. Do not take more than one Proquin[®] XR tablet a day, even if you miss a dose.
- If you take too much, call your healthcare provider or get medical help right away.

What should I avoid while taking Proquin[®] XR?

- Proquin[®] XR can make you feel dizzy and lightheaded. Do not drive, operate machinery, or do other activities that require mental alertness or coordination until you know how Proquin[®] XR affects you.
- Avoid sunlamps, tanning beds, and try to limit your time in the sun. Proquin[®] XR can make your skin sensitive to the sun (photosensitivity) and the light from the sunlamps and tanning beds. You could get severe sunburn, blisters or swelling of your skin. If you get any of these symptoms while taking Proquin[®] XR, call your healthcare provider right

- Avoid breastfeeding during treatment with Proquin XR. If you are breastfeeding, you should either stop breastfeeding, or pump and throw away the milk **during treatment and for 24 hours after your last dose** of Proquin XR. See “What should I tell my doctor before taking Proquin XR?”

What are the possible side effects of Proquin® XR?

Proquin® XR can cause side effects that may be serious or even cause death.

- See “**What is the most important information I should know about Proquin® XR?**”
- **Serious allergic reactions.** Allergic reactions can happen in people taking fluoroquinolones, including Proquin® XR, even after only one dose. Stop taking Proquin® XR and get emergency medical help right away if you get any of the following symptoms of a severe allergic reaction:
 - rash or blistering and break down of your skin
 - trouble breathing or swallowing
 - swelling of the lips, tongue, face
 - throat tightness, hoarseness
 - rapid heartbeat
 - seizures
 - yellowing of the skin or eyes. Stop taking Proquin® XR and tell your healthcare provider right away if you get yellowing of your skin or white part of your eyes, or if you have dark urine. These can be signs of a serious reaction to Proquin® XR (a liver problem).
 - shortness of breath, tiredness, unexplained bruising and bleeding.
- **Central Nervous System Effects:** Seizures can happen in people who take fluoroquinolone antibiotics, including Proquin® XR. Tell your healthcare provider if you have a history of seizures. Ask your healthcare provider whether taking Proquin® XR will change your risk of having a seizure. Seizures have been reported in patients taking fluoroquinolone antibiotics including Proquin® XR.

Central Nervous System (CNS) side effects may happen as soon as after taking the first dose of Proquin® XR. Talk to your healthcare provider right away if you get any of these side effects, or other changes in mood or behavior:

- feel dizzy
- seizures
- hear voices, see things, or sense things that are not there (hallucinations)
- feel restless
- tremors
- feel anxious or nervous
- confusion
- depression
- trouble sleeping

- nightmares
- feel lightheadedness
- feel more suspicious (paranoia)
- suicidal thoughts or acts
- **Intestine infection** (Pseudomembranous colitis). Pseudomembranous colitis can happen with most antibiotics, including Proquin[®] XR. Call your healthcare provider right away if you get watery diarrhea, diarrhea that does not go away, or bloody stools. You may have stomach cramps and a fever. Pseudomembranous colitis can happen 2 or more months after you have finished your antibiotic.
- **Changes in sensation and possible nerve damage** (Peripheral Neuropathy). Damage to the nerves in arms, hands, legs, or feet can happen in people taking fluoroquinolones, including Proquin[®] XR. Talk with your healthcare provider right away if you get any of the following symptoms of peripheral neuropathy in your arms, hands, legs, or feet:
 - pain
 - burning
 - tingling
 - numbness
 - weakness

Proquin[®] XR may need to be stopped to prevent nerve damage.

- **Sensitivity to sunlight** (photosensitivity). See “**What should I avoid while taking Proquin[®] XR?**”
- **Low blood sugar** (hypoglycemia). People taking fluoroquinolone medicines such as Proquin[®] XR with oral anti-diabetes medicines glyburide (Micronase[®], Glynase[®], Diabeta[®], Glucovance[®]) can get low blood sugar (hypoglycemia). Follow your healthcare provider’s instructions for how often to check your blood sugar. Tell your healthcare provider if you get low blood sugar with Proquin[®] XR. Your antibiotic medicine may need to be changed.

The most common side effects of Proquin[®] XR include:

- yeast infection
- inflamed nose and throat
- headache
- feeling an urgent need to urinate

These are not all the possible side effects of Proquin[®] XR. Tell your healthcare provider about any side effect that bothers you or that does not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1--800-FDA-1088.

How should I store Proquin[®] XR?

- Store Proquin[®] XR at 59 °F to 86°F (15°C to 30°C).

Keep Proquin[®] XR and all medicines out of the reach of children.

General information about Proquin[®] XR

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Proquin[®] XR for a condition for which it is not prescribed. Do not share Proquin[®] XR with other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about Proquin[®] XR. If you would like more information about Proquin[®] XR, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about Proquin[®] XR that is written for healthcare professionals. For more information go to www.proquinxr.com or call 1-866-458-6389.

What are the ingredients in Proquin[®] XR?

- Active ingredient: ciprofloxacin hydrochloride monohydrate
- Inactive ingredient: povidone, magnesium stearate, polyethylene oxide and film coating (Opadry Blue)

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Rx Only

Proquin[®] XR

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This Medication Guide has been approved by the U.S. Food and Drug Administration.