

## 17 PATIENT COUNSELING INFORMATION

See FDA-approved Medication Guide (17.2)

### 17.1 Dosing Instructions

Patients should be instructed to:

- Take all of the medication as directed.
- Take no more of the medication than the amount prescribed.
- Take with food to minimize possible gastrointestinal irritation.

If a dose is missed, patients should also be instructed not to double the next dose. If more than 4 hours has elapsed since the missed dose, the patient should wait and take the next dose as previously scheduled.

### 17.2 FDA-Approved Medication Guide

## MEDICATION GUIDE

**QUALAQUIN<sup>®</sup>**  
(kwol-a-kwin)

**(Quinine sulfate) Capsules**

Read the Medication Guide that comes with QUALAQUIN<sup>®</sup> 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 treatment. You and your healthcare provider should talk about QUALAQUIN<sup>®</sup> when you start taking it and at regular checkups. QUALAQUIN<sup>®</sup> is not approved for the treatment of night-time leg cramps.

**What is the most important information I should know about QUALAQUIN<sup>®</sup>?**

**QUALAQUIN<sup>®</sup> used to treat or prevent leg cramps may cause serious side effects or even death.**

- QUALAQUIN<sup>®</sup> may cause your blood cell (platelet) count to drop causing serious bleeding problems. In some people, serious kidney problems can happen.
- QUALAQUIN<sup>®</sup> may cause problems with your heart rhythm that can lead to death.
- QUALAQUIN<sup>®</sup> may cause serious allergic reactions.

### **Call your healthcare provider right away if you have:**

- easy bruising
- severe nose bleed
- blood in urine or stool
- bleeding gums
- appearance of unusual purple, brown or red spots on your skin (bleeding under your skin)
- rash
- hives
- severe itching
- severe flushing
- swelling of your face
- trouble breathing
- chest pain
- rapid heartbeat
- irregular heart rhythm
- weakness
- sweating
- nervousness

Taking QUALAQUIN<sup>®</sup> with some other medicines can increase the chance of serious side effects. Tell your health-care provider if you take any other medicines.

Certain medicines can cause the blood levels of QUALAQUIN<sup>®</sup> to be too high or too low in your body. **It is important for you to tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements.**

QUALAQUIN<sup>®</sup> and other medicines may affect each other causing serious side effects or death. Even medicines that you may take for a short period of time, such as antibiotics, can mix in your blood with QUALAQUIN<sup>®</sup> and cause serious side effects or death. **Do not start taking a new medicine without telling your healthcare provider or pharmacist.**

### **What is QUALAQUIN<sup>®</sup>?**

QUALAQUIN<sup>®</sup> is a prescription medication used to treat malaria (uncomplicated) caused by the parasite *Plasmodium falciparum*.

### **QUALAQUIN<sup>®</sup> is Not approved to:**

- Prevent malaria
- Treat severe or complicated malaria
- Prevent or treat night-time leg cramps

It is not known if QUALAQUIN<sup>®</sup> is safe and works in children younger than 16 years old.

### **Who should not take QUALAQUIN<sup>®</sup>?**

#### **Do not take QUALAQUIN<sup>®</sup> if you have:**

- certain heart rhythm problems (atrial fibrillation) or abnormal electrocardiogram (ECG) (QT prolongation).
- low levels of an enzyme called Glucose-6-phosphate dehydrogenase (G6PD).
- an autoimmune disease (myasthenia gravis) that leads to muscle weakness.
- had allergic reactions to quinine, quinidine, or mefloquine (Lariam<sup>®</sup>).
- had serious side effects to quinine (QUALAQUIN<sup>®</sup>), such as low platelets, which are necessary for your blood to clot.
- an inflammation of the nerve important for vision (optic neuritis).

### **What should I tell my healthcare provider before starting QUALAQUIN<sup>®</sup>?**

Before you take QUALAQUIN<sup>®</sup>, tell your health-care provider if you:

- Have heart problems.
- Have kidney problems.

- Have liver problems.
- Have any other medical condition.
- Are pregnant or could be pregnant. Treatment of malaria is important because it can be a serious disease for a pregnant woman and her unborn baby. Your healthcare provider can tell you more about the benefits and risks of taking this medication during pregnancy. Low blood sugar (hypoglycemia) can be seen in pregnant women while taking QUALAQUIN<sup>®</sup>. This can include sweating, weakness, nausea, vomiting, or confusion. You and your healthcare provider can decide if QUALAQUIN<sup>®</sup> is right for you.
- Are breast-feeding. Small amounts of QUALAQUIN<sup>®</sup> can pass into your breast milk. You and your healthcare provider can decide if you should breastfeed while taking QUALAQUIN<sup>®</sup>.

**Tell your healthcare provider about all the medicines you take, including prescription medicines, vitamins and herbal supplements.**

### **How should I take QUALAQUIN<sup>®</sup>?**

- Take QUALAQUIN<sup>®</sup> exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how many QUALAQUIN<sup>®</sup> capsules to take and when to take them.
- To lower the chance of stomach upset, take QUALAQUIN<sup>®</sup> **with food**.
- Finish all the QUALAQUIN<sup>®</sup> that is prescribed even if you feel better. **Do not** stop taking the medication without talking to your healthcare provider.
- **Do not** take more than the amount prescribed. **Do not** take more than 2 capsules at one time or more than 3 doses in one day. If you take more than the prescribed dose, call your healthcare provider right away.
- If you forget to take QUALAQUIN<sup>®</sup>, **do not** double the next dose. If it has been more than 4 hours since the missed dose, just wait and take the regular dose at the next scheduled time. Call your healthcare provider if you are not sure what to do.
- If you take too much QUALAQUIN<sup>®</sup>, call your healthcare provider or go to the nearest emergency room right away.

### **Call your healthcare provider right away if:**

- If you feel worse, or if you do not start feeling better within 1 or 2 days of starting to take QUALAQUIN<sup>®</sup>.
- If your fever comes back after finishing treatment with QUALAQUIN<sup>®</sup>.

### **What are the possible side effects of QUALAQUIN<sup>®</sup>?**

#### **QUALAQUIN<sup>®</sup> may cause serious side effects.**

- See “What is the most important information I should know about QUALAQUIN<sup>®</sup>” section.
- Low blood sugar (hypoglycemia). This can include sweating, weakness, nausea, vomiting, or confusion.

#### Common side effects with QUALAQUIN<sup>®</sup> include:

- |                        |                                |
|------------------------|--------------------------------|
| • headache             | • hearing loss                 |
| • sweating             | • dizziness (vertigo)          |
| • flushing             | • blurred vision               |
| • nausea               | • changes in how you see color |
| • ringing in your ears | • vomiting                     |
| • diarrhea             | • stomach pain                 |
| • deafness             | • blindness                    |

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of QUALAQUIN<sup>®</sup>. For more information, ask your healthcare provider or pharmacist.

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 QUALAQUIN®?**

- Keep the capsules in a tightly closed container.
- Do not refrigerate or freeze.
- Store at 20°C to 25°C (68°F to 77°F).

**Keep QUALAQUIN® and all medicines out of the reach of children.**

### **General Information about QUALAQUIN®**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use QUALAQUIN® for a condition for which it was not prescribed. Do not give QUALAQUIN® to 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 QUALAQUIN®. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about QUALAQUIN® that is written for healthcare professionals.

For more information, go to [www.QUALAQUIN.com](http://www.QUALAQUIN.com) or call 1-888-351-3786.

### **What are the ingredients in QUALAQUIN®?**

**Active Ingredients:** Quinine Sulfate, USP

**Inactive Ingredients:** Corn starch, magnesium stearate, talc

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

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by:

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