

MEDICATION GUIDE
QUALAQUIN[®]
(kwol-a-kwin)

(Quinine Capsules, USP)

Read the Medication Guide that comes with QUALAQUIN[®] 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[®] when you start taking it and at regular checkups. QUALAQUIN[®] is not approved for the treatment of night time leg cramps.

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

QUALAQUIN[®] used to treat or prevent leg cramps may cause serious side effects or even death.

- QUALAQUIN[®] may cause your blood cell (platelet) count to be low causing serious bleeding problems. In some cases, kidney injury can occur.
- QUALAQUIN[®] may cause serious allergic reactions.
- QUALAQUIN[®] may cause problems with your heart rhythm that can lead to death.

Call your healthcare provider right away if you have:

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

Taking QUALAQUIN[®] with some other medicines can increase the chance of serious side effects. Tell your healthcare provider if you take other medicines.

Certain medicines can cause the blood levels of QUALAQUIN[®] 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[®] 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[®] and cause serious side effects or death. Do not start taking a new medicine without talking to your healthcare provider or pharmacist.

What is QUALAQUIN[®]?

QUALAQUIN[®] is a prescription medication used to treat malaria (uncomplicated) caused by the parasite *Plasmodium falciparum*.

QUALAQUIN[®] is NOT approved to:

- prevent malaria
- treat severe or complicated malaria
- prevent or treat night-time leg cramps

It is not known if QUALAQUIN[®] is safe and works in children younger than 16 years old.

Who should not take QUALAQUIN[®]?

Do not take QUALAQUIN[®] if you:

- have heart rhythm problems (QT interval prolongation) or an abnormal electrocardiogram (ECG)
- have low levels of an enzyme (Glucose-6-phosphate dehydrogenase or G-6-PD) that help red cells work normally
- have an autoimmune disease (Myasthenia Gravis) that leads to muscle weakness
- have had allergic reactions to quinine, quinidine, or mefloquine (Lariam[®])
- have had serious side effects to QUALAQUIN[®], such as lowered platelets, which are necessary for your blood to clot
- have an inflammation of the nerve (Optic Neuritis) important for vision

What should I tell my healthcare provider before starting QUALAQUIN[®]?

Before you start taking QUALAQUIN[®], tell your doctor or health care provider if you:

- have heart problems
- have kidney problems
- have liver problems
- have any other medical conditions
- 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) has been seen in pregnant women while taking QUALAQUIN[®]. This can include sweating, weakness, nausea, vomiting, or confusion. You and your healthcare provider can decide if you should take QUALAQUIN[®].
- are breast-feeding. Small amounts of QUALAQUIN[®] can pass into the breast milk. You and your healthcare provider can decide if you should breastfeed while taking QUALAQUIN[®].

Tell your healthcare provider about all the medicines you take, including prescription medicines, vitamins, and herbal supplements. See “What is the most important information I should know about QUALAQUIN[®]?”

How should I take QUALAQUIN[®]?

Take QUALAQUIN[®] exactly as your healthcare provider tells you to take it.

- Your healthcare provider will tell you how many QUALAQUIN[®] to take and when to take it.
- To lower the chance of stomach upset, take QUALAQUIN[®] with food.
- Finish all the QUALAQUIN[®] 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[®], 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[®], call your healthcare provider or go to the closest hospital emergency room right away.

Call your healthcare provider right away if:

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

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

QUALAQUIN[®] may cause serious side effects.

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

Common side effects with QUALAQUIN[®] include:

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| <ul style="list-style-type: none"> • Headache • Sweating • Flushing • Nausea • Ringing in your ears | <ul style="list-style-type: none"> • Hearing loss • Dizziness (vertigo) • Blurred Vision • Change in how you see color |
|--|--|

Less common side effects include:

- 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[®]. 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 QUALAQUIN[®] out of reach of children.

- Keep the capsules in a tightly closed container.

- Do not refrigerate or freeze.
- Store at 20° to 25°C (68° to 77°F).

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 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.

Manufactured for:

AR SCIENTIFIC, INC.

Philadelphia, PA 19124 USA

by:

MUTUAL PHARMACEUTICAL COMPANY, INC.

Philadelphia, PA 19124 USA

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Application
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Submission
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Submitter Name

Product Name

NDA-21799

SUPPL-14

AR HOLDING CO
INC

QUALAQUIN SULFATE
CAPSULES 324MG

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OZLEM A BELEN
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