

MEDICATION GUIDE

QUININE SULFATE CAPSULES

for oral use

Read the Medication Guide that comes with quinine sulfate capsules 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 quinine sulfate capsules when you start taking it and at regular checkups. Quinine sulfate capsules are not approved for the prevention or treatment of night-time leg cramps.

What is the most important information I should know about quinine sulfate capsules?

Quinine sulfate capsules used to treat or prevent leg cramps may cause serious side effects or even death.

Quinine sulfate capsules may cause:

- your blood cell (platelet) count to drop causing serious bleeding problems. In some people, serious kidney problems can happen.
- problems with your heart rhythm that can lead to death.
- serious allergic reactions.

Call your healthcare provider right away if you have:

- easy bruising
- severe nose bleed
- blood in urine or stool
- bleeding gums
- 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

Quinine sulfate capsules can have other serious side effects. See **“What are the possible side effects of quinine sulfate capsules?”**

What are quinine sulfate capsules?

Quinine sulfate capsules are a prescription medicine used to treat uncomplicated malaria caused by the parasite *Plasmodium falciparum*.

Quinine sulfate capsules are not approved to:

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

It is not known if quinine sulfate capsules are safe and effective in children under 16 years of age.

Who should not take quinine sulfate capsules?

Do not take quinine sulfate capsules if you have:

- changes in the electrical activity of your heart called **QT prolongation**.
- had allergic reactions to quinine (the active ingredient in quinine sulfate capsules), such as low platelets, which are necessary for your blood to clot.
- had allergic reactions to mefloquine (Lariam) or quinidine.
- an autoimmune disease (myasthenia gravis) that leads to muscle weakness.
- an inflammation of the nerve important for vision (optic neuritis).

What should I tell my healthcare provider before taking quinine sulfate capsules?

Before taking quinine sulfate capsules, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems.
- have kidney problems.
- have liver problems.
- are pregnant or plan to become pregnant. Treatment of malaria is important because it can be a serious disease for a pregnant woman and her unborn baby. Talk to your healthcare provider about the benefits and risks of taking quinine sulfate capsules during pregnancy. Low blood sugar (hypoglycemia) can happen in pregnant women while taking quinine sulfate capsules. Signs and symptoms of low blood sugar can include sweating, weakness, nausea, vomiting, and confusion. You and your healthcare provider can decide if quinine sulfate capsules are right for you.
- are breastfeeding or plan to breastfeed. Quinine sulfate capsules can pass into your breast milk. You should talk with your healthcare provider about the best way to feed your baby while taking quinine sulfate capsules.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Quinine sulfate capsules and other medicines may affect each other causing serious side effects. Certain medicines can cause the blood levels of quinine sulfate capsules to be too high or too low in

your body.

Do not start taking a new medicine without telling your healthcare provider or pharmacist. Even medicines that you may take for a short period of time, such as antibiotics, can mix in your blood with quinine sulfate capsules and cause serious side effects or death.

How should I take quinine sulfate capsules?

- Take quinine sulfate capsules exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how many quinine sulfate capsules to take and when to take them.
- Take quinine sulfate capsules **with food** to lower your chance of having an upset stomach.
- Do not skip any doses or stop taking quinine sulfate capsules without first talking to your healthcare provider, even if you feel better.
- **Do not** take more quinine sulfate capsules than prescribed.
- If you miss a dose of quinine sulfate capsules, **do not** double the next dose to make up for a missed dose. If it has been more than **4 hours** since the missed dose, take your next dose at the next scheduled time. Call your healthcare provider if you are not sure what to do.
- If you take too much quinine sulfate capsules, call your healthcare provider or go to the nearest emergency room right away.

What are the possible side effects of quinine sulfate capsules?

Quinine sulfate capsules may cause serious side effects, including:

- See “**What is the most important information I should know about Quinine sulfate capsules**”.
- **Heart rhythm problems** (atrial fibrillation and atrial flutter).
- **Low blood sugar (hypoglycemia)**. Signs and symptoms of low blood sugar can include sweating, weakness, nausea, vomiting, and confusion.

The most common side effects of quinine sulfate capsules include:

- headache
- sweating
- flushing
- nausea
- ringing in your ears
- diarrhea
- deafness
- problems with heart rhythm or conduction
- hearing loss
- dizziness (vertigo)
- blurred vision
- changes in how you see color
- vomiting
- stomach pain
- 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 quinine sulfate capsules. 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 quinine sulfate capsules?

- Keep the capsules in a tightly closed container.
- Store quinine sulfate capsules at room temperature between 68°F to 77°F (20°C to 25°C).

Keep quinine sulfate capsules and all medicines out of the reach of children.

General information about the safe and effective use of quinine sulfate capsules.

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

What are the ingredients in quinine sulfate capsules?

Active Ingredients: quinine sulfate, USP

Inactive Ingredients: corn starch, magnesium stearate, talc

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For more information about quinine sulfate capsules, call 1-800-406-7984.

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