

Quinine Sulfate 200mg tablets

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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1 What Quinine sulfate tablets are and what they are used for

Quinine sulfate belongs to a group of medicines called anti-protozoal agents and they are used to treat:

- malaria
- and prevent night cramps in adults and the elderly when sleep is regularly disrupted

2 Before you take

Do not take Quinine sulfate tablets and **tell your doctor** if you have:

- an **allergy** (hypersensitivity) to quinine (including that in tonic waters or other beverages), quinoline or any of the other ingredients (see section 6)
- **blood in your urine**
- **ringing in your ears**
- suffer from muscle weakness (**myasthenia gravis**)
- **problems with your eyes** or difficulty seeing

Check with your doctor or pharmacist before taking Quinine sulfate tablets if you:

- have **irregular heart beats** or other **heart disease**
- have had **malaria** for a long time
- suffer from severe glucose-6-phosphate dehydrogenase deficiency (**G6PD**), this can cause episodes of anaemia after eating certain foods such as fava beans (favism) or certain drugs including drugs to prevent malaria and dapsone

You should not take more than the prescribed dose as a condition called 'cinchonism' may occur even with normal doses. Please see section 4 'Possible side effects' for symptoms of cinchonism and tell your doctor if you experience any of them.

Taking other medicines

Please **tell your doctor or pharmacist** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:

- anticoagulants (to stop your blood from clotting)
- cardiac glycosides (for your heart such as digoxin)
- chloroquine, mefloquine, artemether with lumefantrine or primaquine (also to treat malaria)
- cimetidine (to treat stomach ulcers or acid reflux and indigestion)
- amantadine (to treat Parkinsons Disease or some viral infections)
- ciclosporin (to prevent transplant rejection)
- flecainide, quinidine or amiodarone (to treat irregular heart beats)
- terfenadine (for allergic reactions)
- pimozone or thioridazine (to treat some mental disorders)
- moxifloxacin rifampicin or antifungals (to treat infections)
- medicines to treat diabetes
- suxamethonium (muscle relaxant)
- HIV medicines
- barbiturates, carbamazepine or phenytoin (used in epilepsy)

Pregnancy and breast-feeding

You should not take Quinine sulfate tablets if you are pregnant, planning to become pregnant or breast-feeding unless advised to by your doctor. **Quinine sulfate tablets should not be used for night cramps during pregnancy.**

Driving and using machines

Quinine sulfate tablets may affect your vision. Make sure you are not affected before you drive or operate machinery.

3 How to take

Always take Quinine sulfate tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

Swallow the tablets with water.

Doses:

• **Malaria** (you may be given another medicine for malaria with or after this course of quinine):

Adults (including elderly) and children over 12 years - 600mg every eight hours for 5-7 days

Children under 12 years - 10mg per kg of body weight every eight hours for 7 days

If you have kidney or liver disease you may be given a different dose.

• **Night cramps:**

Adults (including elderly) - 200mg at bedtime. It may take up to 4 weeks before you notice any reduction in the frequency of leg cramps.

If you take more than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Symptoms include loss of consciousness, difficulty breathing, changes in heart beat, fits, 'ringing' in the ears, loss of hearing, headache, feeling or being sick and changes in vision.

If you forget to take the tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

4 Possible side effects

Like all medicines, Quinine sulfate tablets can cause side effects, although not everybody gets them.

Contact your doctor at once if the following effects occur:

- **allergic reactions** – itchy skin rash, swelling of the lips, face, throat or tongue, flushing, fever, asthma or sensitivity to light
- **cinchonism** – abdominal pain, diarrhoea, disturbed vision (blurred vision, changes in colour perception or field of vision, total blindness), headache, feeling or being sick, ringing in the ears or impaired hearing, rashes, loss of consciousness, fits, shock due to heart problems, irregular heart beats, death. If these occur while taking Quinine sulfate tablets for leg cramps, treatment should be stopped and a doctor contacted straight away.
- changes to blood cells, if you notice that you are bruising or bleeding easily, have frequent nose bleeds, or you have more sore throats and infections than usual tell your doctor who may want to give you a blood test.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

- diarrhoea, feeling or being sick, abdominal pain, low blood sugar.
- muscle weakness, excitement, agitation, 'spinning' sensation, confusion, loss of consciousness, coma, death.
- headache, changes in vision, 'ringing' in the ears, loss of hearing.
- swollen, itchy, flaky, red or raised patches of skin, rashes, sensitivity to light.
- aggravation of Myasthenia gravis.
- kidney damage, water retention, slowed heart rate, changes in heart rhythm and the way the heart beats, eczema, miscarriages (at very high concentrations), difficulty breathing.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store

Keep out of the reach and sight of children.

Store below 25°C in a dry place

Do not use Quinine sulfate tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What Quinine sulfate tablets contain

- The active substance (the ingredient that makes the tablet work) is 200mg quinine sulfate.
- The other ingredients are sodium lauryl sulfate, povidone, microcrystalline cellulose (E460), croscarmellose sodium, magnesium stearate, hydrogenated vegetable oil.
- The coating contains hydroxypropylmethyl cellulose, hydroxypropyl cellulose, medium chain triglycerides, macrogol 3350, titanium dioxide (E171).

What Quinine sulfate tablets look like and contents of the pack

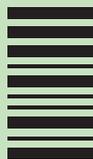
Quinine sulfate tablets are white, circular, film-coated tablets.

Pack sizes are 28 tablets

Marketing Authorisation Holder and Manufacturer

Actavis, Barnstaple, EX32 8NS, UK

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