Quinine Sulfate 300mg Tablets

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

2 What you need to know before you take Quinine sulfate tablets

Do not take Quinine sulfate tablets if:
- you are allergic to quinine (including that in tonic waters or other beverages), quinoline or any of the other ingredients of this medicine (listed in section 6)
- blood in your urine
- ringing in your ears
- suffer from muscle weakness (myasthenia gravis)
- problems with your eyes or difficulty seeing
- you have been told you have a disorder affecting the red blood cells (haemolysis).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Quinine sulfate tablets:
- if you have irregular heartbeats or other heart disease
- if you have had malaria for a long time
- if you 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
- if you were born with or have any condition that causes an abnormal heart rhythm.

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.

Other medicines and Quinine sulfate tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Especially:
- anticoagulants (to stop your blood from clotting)
- cardiac glycosides (for your heart such as digoxin)
- chloroquine, mefloquine, artemether with lumefantrine, primamquine, halofantrine (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)
- felacainide, quinidine or amiodarone (to treat irregular heartbeats)
- terfenadine (for allergic reactions)
- pimozide or thiordizone (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)
- medicines which are known to cause disturbances in heart rhythm
- levacyclomethadol (a pain killer).

Pregnancy, breast-feeding and fertility

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 and cause vertigo (dizziness or spinning sensation). Make sure you are not affected before you drive or operate machinery.
3 How to take Quinine sulfate tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the tablets with water.

The recommended dose is:
- 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) - 300mg at bedtime. It may take up to 4 weeks before you notice any reduction in the frequency of leg cramps.

If you take more Quinine sulfate tablets 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 and heart function, kidney failure, fits, ‘ringing’ in the ears, loss of hearing, headache, being sick, changes in vision, low blood potassium (causing muscle twitching/weakness or abnormal heart rhythm) and low blood sugar, and sweating. Some of these side effects can be fatal. High doses of quinine may also cause miscarriage in pregnant women.

If you forget to take Quinine sulfate 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.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4 Possible side effect

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor immediately 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
- sores in the mouth, nose, and eyes, a skin rash, and blistering (Stevens Johnson syndrome)
- enchinomus - 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 heartbeat, 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 as seen in blood or urine tests, 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.
- tightness in chest, difficulty breathing or wheezing
- 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 (disorder characterised by muscle weakness, difficulty chewing or swallowing and slurred speech).
- kidney damage, kidney failure, low production of urine, water retention, slowed heart rate, changes in heart rhythm and the way the heartbeats, a fall in blood pressure and weak pulse rate, 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 Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5 How to store Quinine sulfate tablets

Keep out of the sight and reach 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.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Quinine sulfate tablets contain
- The active substance (the ingredient that makes the tablet work) is 300mg quinine sulfate.
- The other ingredients are sodium lauryl sulfate, povidone, microcrystalline cellulose (E460), croscarmellose sodium, magnesium stearate, hydrogenated vegetable oil.
- The coating contains hypromellose, hydroxypropyl cellulose, medium chain triglycerides, macrogl 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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