

**Package leaflet: Information for the user**  
**Quinine Sulfate 300mg Coated Tablets**

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.



**What is in this leaflet**

1. What Quinine Sulfate Tablets are and what they are used for
2. What you need to know before you take Quinine Sulfate Tablets
3. How to take Quinine Sulfate Tablets
4. Possible side effects
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**1. What Quinine Sulfate Tablets are and what they are used for**

The name of your medicine is Quinine Sulfate 300mg Coated Tablets. Quinine Sulfate Tablets contain the anti-malarial drug quinine sulfate and are used to treat a type of malaria known as falciparum malaria (malignant malaria). Malaria is a disease caused by infection with a malaria parasite. This is carried by mosquitoes, which flourish in tropical and subtropical countries. Human beings become infected as a result of being bitten by malaria carrying mosquitoes. Quinine sulfate has a relaxant action on skeletal muscle. Your doctor may have prescribed this medicine for the treatment of night leg cramps.

**2. What you need to know before you take Quinine Sulfate Tablets**

**Do not take Quinine Sulfate Tablets:**

- if you are allergic to quinine or any of the other ingredients of this medicine (listed in section 6)
- if you have problems with your eye sight
- if you suffer from tinnitus (ringing noises in the ear)
- if you have blood in the urine (or have had during a previous attack of malaria)
- if you have been told you have haemolysis (a disorder affecting the red blood cells)
- if you suffer from myasthenia gravis (a disease characterised by weakness of certain groups of muscles)
- if you are pregnant or breast-feeding, unless the benefits outweigh the risks

**Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Quinine Sulfate Tablets, if you suffer from, or have ever had:

- an enzyme deficiency, called glucose-6-phosphate dehydrogenase deficiency
- your doctor has told you that you have a blood condition known as hypoprothrombinaemia
- irregular heart beat or other heart problems
- you have been told by your doctor that you have an intolerance to some sugars
- an adverse reaction to quinine, including that found in tonic water and other beverages. Quinine may cause thrombocytopenia, a blood condition which causes you to bleed and bruise easily

Tell your doctor if you were born with or have any condition that causes an abnormal heart rhythm.

**Other medicines and Quinine Sulfate Tablets**

Your medicine may interfere with other medicines that you are taking. Tell your doctor or pharmacist if you are taking,

have recently taken or might take any other medicines. Do not take with:

- Chloroquine, Mefloquine, Halofantrine (used to treat malaria)
- Pimozide and thioridazine (used to treat depressive illnesses)
- Astemizole, Terfenadine (used to treat allergies)
- Amiodarone (used to treat heart conditions)
- levacetylmethadol (a pain killer)

Tell your doctor if you are taking:

- Medicines which are known to cause disturbances in heart rhythm
- Barbiturates or carbamazepine (medicines to treat epilepsy)

Dose adjustment may be needed if you take the following drugs:

- Antibacterials e.g. rifampicin (used to treat tuberculosis and leprosy) and moxifloxacin (used to treat chest infections and sinusitis)
- Digoxin, Flecainide and Quinidine (used to treat heart conditions)
- Anticoagulants e.g. warfarin (used to prevent blood clots)
- Antifungals e.g. ketoconazole (used to treat fungal infections)
- HIV protease inhibitors e.g. nelfinavir (used in the treatment of AIDS)
- Barbiturates, carbamazepine and phenytoin (used to treat epilepsy)
- Cyclosporin, used in the treatment of rheumatoid arthritis and in transplant surgery
- Tablets used to treat diabetes such as gliclazide and tolbutamide
- Suxamethonium (used during anaesthesia)
- Amantadine, used for Parkinson's disease and to treat virus infections

Your doctor will advise you about this.

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. You should not take quinine sulfate when you are pregnant or breast-feeding, unless the benefits outweigh the risks. This medicine should not be used to treat cramps during pregnancy.

Large doses of quinine can cause foetal abnormalities or induce abortion. You should not breast-feed a baby that might have glucose-6-phosphate dehydrogenase (G6PD) deficiency.

**Driving and using machines**

This medicine may cause visual disturbances and vertigo. If affected, do not drive or operate any tools or machines.

**Quinine Sulfate Tablets contain lactose and methyl hydroxyl benzoate**

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains methyl hydroxyl benzoate (E218) which may cause allergic reactions (possibly delayed).

### 3. How to take Quinine Sulfate Tablets

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

**Your medicine should be taken by mouth as follows:  
For the treatment of Falciparum Malaria:**

**Adults:** The recommended dose is 600mg (two 300mg tablets) every eight hours for seven days.

**Children:** The recommended dose is 10mg quinine sulfate per kg of body weight, given every eight hours for seven days.

**For the treatment of Night Cramps:**

**Adults (including the elderly):** 300mg (one tablet) at bedtime.

**Children:** This medicine should not be used for the relief of night leg cramps in children under 10 years of age.

**If you take more Quinine Sulfate Tablets than you should**  
If you take too many tablets tell a doctor or hospital casualty department straight away. Take your medicine with you.

**If you forget to take Quinine Sulfate Tablets**

If you do forget to take a dose of your medicine at the correct time, take as soon as you remember, then carry on as before. Do not take a double dose to make up for a forgotten dose.

Keep taking this medicine until your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop taking the medicine, your condition may re-occur or get worse.

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

### 4. Possible side effects

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

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking this medicine. All medicines can have some unwanted effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Stop taking your medicine and tell your doctor immediately, or go to accident and emergency if you notice any of the following:**

- Shortness of breath or difficulty breathing
- Asthma
- Hot flushing or rash of the skin, itching, or swelling
- Shock
- Difficulty swallowing
- Tiredness, weakness
- Sensitivity to sunlight
- Increased or unexplained bruising, or bleeding more readily, or more frequent nose bleeds
- Signs of frequent infections such as fever, sore throat or mouth ulcers
- Irregular heart beats to heart problems
- Decreased urine production or no urine, blood, or reddish colour in the urine
- Face swelling

Quinine may cause 'cinchonism' which generally occurs in overdose, but may rarely also occur at normal doses.

These can be very severe side effects of your medicine. If you have them you may have had an allergic reaction to quinine. You may need urgent medical attention. All of these side effects are very rare.

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- Ringing in the ears, loss of hearing
- Headache, dizziness, confusion
- Feeling or being sick (nausea or vomiting)
- Diarrhoea, stomach ache
- Blurred vision (mild), problems with colour vision or tunnel vision
- Low blood sugar

These are some of the more common side effects of quinine and are usually associated with long-term

treatment with Quinine Sulfate Tablets.

The list of side effects mentioned above is not complete. If you should suffer from any of these side effects or any other undesired effect please tell your doctor or pharmacist. Do not be alarmed by this list of possible side effects. You may not experience any of them.

**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 national reporting systems listed below:  
United Kingdom:  
Yellow Card Scheme  
Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App store

Malta: ADR Reporting,  
Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

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

### 5. How to store Quinine Sulfate Tablets

Keep this medicine out of the sight and reach of children. Do not use your medicine after the expiry date shown on the carton. The expiry date refers to the last day of that month. Do not store above 25°C.

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

### 6. Contents of the pack and other information

**What Quinine Sulfate Tablets contain**

The active substance is quinine sulfate. These tablets contain 300mg of the active substance. The other ingredients are lactose monohydrate, maize starch, microcrystalline cellulose, sodium starch glycolate, povidone, magnesium stearate, opaglos (ethanol, yellow carnauba wax and white beeswax), sucrose, calcium carbonate, talc, titanium dioxide (E171), acacia spray-dried, methyl hydroxyl benzoate (E218), and carnauba wax.

**What Quinine Sulfate Tablets look like and contents of the pack**

Quinine Sulfate 300MG Coated Tablets are white, circular, sugar-coated tablets.

The tablets are available in packs of 28 tablets. This leaflet is a summary. It does not contain the complete information about your medicine. If you have any further questions or are not sure about anything, ask your doctor or pharmacist who have access to additional information.

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder:** Wockhardt UK Limited, Ash Road North, Wrexham, LL13 9UF, UK.  
**Manufacturer:** CP Pharmaceuticals Limited, Ash Road North, Wrexham, LL13 9UF, UK.

**Other sources of information**

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only). Please be ready to give the following information:

Product name	Reference number
Quinine Sulfate 300mg Coated Tablets	PL 29831/0182

This is a service provided by the Royal National Institute of Blind People

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