

## Package leaflet: Information for the user

### Quinine Sulphate 300 mg film-coated tablets quinine sulphate

**Read all of this leaflet carefully before you start taking 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, ask your doctor, pharmacist or nurse.
- 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 Sulphate is and what it is used for**
- 2. What you need to know before you take Quinine Sulphate**
- 3. How to take Quinine Sulphate**
- 4. Possible side effects**
- 5. How to store Quinine Sulphate**
- 6. Contents of the pack and other information**

#### **1. What Quinine Sulphate is and what it is used for**

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

- treat malaria
- treat and prevent nocturnal (night time) leg cramps in the adults and the elderly when sleep is regularly disrupted.

#### **2. What you need to know before you take Quinine Sulphate**

##### **Do not take Quinine Sulphate:**

- if you are allergic to quinine sulphate or any of the other ingredients of this medicine (listed in section 6)
- if you have **blood in your urine**
- if you have **ringing or buzzing in your ears** (tinnitus)
- if you have **problems with your eyes** or difficulty seeing
- if you have muscle weakness (**myasthenia gravis**)
- if you have a history of decreased levels of platelets (thrombocytopenia). If you are elderly and develop thrombocytopenia you are at risk of a brain haemorrhage
- if you have a history of cardiac arrhythmias (irregular heart rate or rhythm)

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Quinine Sulphate

- if you have **irregular heart beats** 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 or certain drugs during quinine therapy if you have previously experienced any adverse reaction to quinine.

Normal doses of quinine may give rise to cinchonism (refer to section 4 for details of the symptoms associated with cinchonism). Check with your doctor or pharmacist if you notice any of the symptoms of cinchonism.

### **Other medicines and Quinine Sulphate**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Especially:

- ketoconazole or itraconazole (used to treat fungal infections)
- medicines for the treatment of AIDS (HIV protease inhibitors such as indinavir, nelfinavir, ritonavir and saquinavir)
- carbamazepine or phenytoin (used to treat epilepsy)
- sedatives (e.g. diazepam or barbiturates)
- anticoagulants (to stop your blood from clotting)
- cardiac glycosides (for your heart such as digoxin)
- chloroquine, mefloquine, halofantrine, primaquine or artemether with lumefantrine (also to treat malaria)
- cimetidine (to treat stomach ulcers or acid reflux and indigestion)
- amantadine (to treat Parkinson's Disease or some viral infections)
- ciclosporin (to prevent transplant rejection)
- flecainide, amiodarone or quinidine (to treat irregular heart beats)
- terfenadine (for allergic reactions)
- pimozone or thioridazine (to treat some mental disorders)
- moxifloxacin and rifampicin (to treat bacterial infections)
- hypoglycaemics (used in diabetes)
- suxamethonium (for muscle relaxation)
- medicines which are known to cause disturbances in heart rhythm.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant, planning to become pregnant or are breast-feeding ask your doctor or pharmacist for advice before taking this medicine.

Quinine sulphate should not be used during pregnancy to treat leg cramps.

### **Driving and using machines**

Quinine Sulphate may make you feel dizzy and your vision may be blurred. If so, do not drive or operate machinery.

## **3. How to take Quinine Sulphate**

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:**

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

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

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

On completion of a course of quinine sulphate, your doctor may prescribe a different medicine if resistance to quinine is known or suspected.

**• Night cramps:**

**Adults (including elderly)** - 300 mg at bedtime. A reduction in frequency of leg cramps may not be seen for up to 4 weeks. During this time your doctor should monitor you to make sure that the medicine is suitable for you. He/she should monitor you at three-monthly intervals thereafter. From time to time, your doctor may stop treatment with quinine sulphate to see if the condition returns or worsens.

**Use in children and adolescents**

Quinine sulphate is only indicated in children and adolescents for treatment of malaria.

This medicine should not be used in children and adolescents to treat nocturnal leg cramps.

**If you take more Quinine Sulphate 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 of an overdose may include convulsions, nausea, vomiting, tinnitus, deafness, headache, reduced blood pressure, disturbed vision, difficulty breathing and loss of consciousness.

**If you forget to take Quinine Sulphate**

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 effects**

Like all medicines, this medicine 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, difficulty breathing, asthma or sensitivity to light.
- **cinchonism** – in mild cases symptoms include ringing in the ears or impaired hearing, rashes, headache, nausea and disturbed vision. In more severe cases symptoms may include feeling or being sick, abdominal pain, temporary blindness and visual disturbances, respiratory depression, coma and death. If these occur while taking Quinine Sulphate for leg cramps, treatment should be stopped and a doctor contacted straight away.
- **changes to blood cells** - if you notice unexplained bruising or bleeding or have frequent nose bleeds, or you have more sore throats and infections than usual stop taking Quinine Sulphate immediately and consult your doctor. These may be symptoms of thrombocytopenia which is serious and can be life-threatening.

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

- flushing, rash, hives, eczema, itching, sensitivity to light
- low blood glucose levels
- agitation, confusion
- dizziness, headache, excitement, loss of consciousness, coma and death
- altered vision
- ringing in the ears, impaired hearing
- changes in heart beat or rhythm
- diarrhoea, nausea, vomiting and abdominal pain (may occur after long term use)
- low blood pressure
- oedema (retention of fluid in the body)
- liver and kidney damage

- muscle weakness, or an increase in the severity of the muscle weakening disorder, myasthenia gravis
- toxic doses of quinine may cause miscarriage.

### **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 HPRA Pharmacovigilance Website: [www.hpra.ie](http://www.hpra.ie).

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

## **5. How to store Quinine Sulphate**

Keep this medicine out of the sight and reach of children.

Do not store above 25°C and keep in the original packaging.

Do not use this medicine after the expiry date which is stated on the carton and blister after 'EXP'. The expiry date refers to the last day of that month.

Do not throw away any 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 Sulphate 300 mg film-coated tablets contain**

- The active substance is quinine sulphate. Each film-coated tablet contains 300 mg of quinine sulphate.
- The other ingredients are sodium laurilsulfate, povidone, microcrystalline cellulose (E460), croscarmellose sodium, magnesium stearate, vegetable oil.
- The coating contains Hypromellose, hydroxypropyl cellulose, medium chain triglycerides, macrogol 3350, titanium dioxide (E171).

### **What Quinine Sulphate 300 mg film-coated tablets look like and contents of the pack**

Quinine Sulphate 300 mg film-coated tablets are white, circular, biconvex film-coated tablets.

*Pack size:* 28, 30, 56, 60, 84, 90, 100, 112, 120, 168, 180, 250, 500, or 1,000 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

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### **Manufacturer**

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**This leaflet was last revised in July 2021.**