

## **Package leaflet: Information for the user**

### **Quinine Sulfate 200 mg Tablets**

**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 or pharmacist.
- This medicine has been prescribed for you. 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**

- 1. What Quinine Sulfate is and what it is used for**
- 2. What you need to know before you take Quinine Sulfate**
- 3. How to take Quinine Sulfate**
- 4. Possible side effects**
- 5. How to store Quinine Sulfate**
- 6. Contents of the pack and other information**

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

Quinine Sulfate is an antimalarial drug also used for muscle disorders.

Quinine Sulfate is used:

- to prevent night cramps
- for the treatment of chloroquine-resistant malaria.

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

**Do not take Quinine Sulfate:**

- if you are allergic to quinine sulfate or any of the other ingredients of this medicine (listed in section 6).
- if you have kidney problems resulting in the presence of blood in your urine
- if you have inflammation of the optic nerve causing problems with your eye sight
- if you suffer from tinnitus (ringing in the ears)
- if you have myasthenia gravis (a disorder in which the muscles are weak and tire easily)
- if you have problems with your eyes or difficulty seeing.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Quinine Sulfate.

Tell your doctor before you start to take this medicine:

- if you suffer from heart, kidney or liver problems
- if you have irregular heart beats or other heart disease
- if you have had malaria for a long time

- if you suffer from glucose 6-phosphate dehydrogenase (G6PD) deficiency, a rare hereditary disease. 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.

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

### **Other medicines and Quinine Sulfate**

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

Talk to your doctor if you are taking any of the following:

- anticoagulants (to stop your blood from clotting)
- cardiac glycosides (for your heart such as digoxin)
- amiodarone, quinidine or flecainide (used to treat an irregular heartbeat)
- pimozide or thioridazine (used in the treatment of mental illness)
- terfenadine (used in the treatment of allergies)
- moxifloxacin or rifampicin (antibiotics)
- antifungals (to treat infections)
- ciclosporin (used to prevent transplant rejection)
- halofantrine, chloroquine, mefloquine or 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)
- suxamethonium (a muscle relaxant)
- carbamazepine or phenytoin (anticonvulsants)
- antifungal medicines, e.g. fluconazole, itraconazole, ketoconazole
- barbiturates, e.g. phenobarbital
- medicines to prevent blood clots forming, e.g. warfarin
- medicines to treat diabetes e.g. metformin, tolbutamide, glimepiride
- medicines used in the treatment of HIV e.g. ritonavir, indinavir, nelfinavir.
- Medicines which are known to cause disturbances in heart rhythm.
- Barbiturates or carbamazepine (medicines to treat epilepsy).

### **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 by your doctor.

**Quinine Sulfate is not recommended for use during pregnancy for the prevention of night cramps.**

### **Driving and using machines**

Quinine Sulfate may affect your vision or cause vertigo (a feeling of dizziness or “spinning”). If you are affected, DO NOT drive or operate machinery.

### **Quinine Sulfate contains sucrose**

Patients who are intolerant to **sucrose** should note that Quinine Sulfate tablets contain a small amount of sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

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.

If you see another doctor or go into hospital, let them or the staff know what medicines you are taking.

The tablets should be swallowed preferably with a drink of water.

The usual dose is:

#### **Adults (including the elderly)**

- **Prevention of night cramp:**

One 200 mg tablet before going to bed. Do not take more than the prescribed dose.

It may take up to 4 weeks before you see a reduction in the frequency of night time cramps.

Your doctor will monitor the effects of your treatment and adjust it accordingly.

Maximum dose - 300 mg at bedtime.

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

#### **Use in children and adolescents**

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

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

#### **Patients with kidney or liver problems**

A lower dose than the usual adult dose or increased time between doses should be used if you have kidney or liver problems.

#### **If you take more Quinine Sulfate than you should**

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has accidentally swallowed any of the tablets, **contact your nearest hospital casualty department or your doctor immediately.**

An overdose of Quinine Sulfate may cause 'cinchonism'. Early symptoms are:

- tinnitus (ringing in the ears), impaired hearing and vision, headache, feeling sick, being sick, fits
- rashes, confusion, hot and flushed skin.

More severe symptoms include:

- nervous system disorders, stomach problems, shallow breathing, loss of consciousness
- severe eyesight problems including blindness
- effects on the heart, kidney and brain
- shock, low blood sugar.

Large doses can cause abortion.

Please take this leaflet, any remaining tablets, and the container with you to the hospital or doctor so that they know which tablets were consumed.

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

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose. Take the remaining doses at the correct time.

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

## **4. Possible side effects**

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

If any of the following happen, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives)
- unexplained bruising or bleeding.

These are very serious but rare side effects. You may need urgent medical attention or hospitalisation.

**Contact your doctor at once** if the following effects occur:

- **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 heartbeats, 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.
- a serious illness with blistering of the skin, mouth eyes and genitals (Stevens-Johnson Syndrome)

If you feel unwell whilst taking Quinine Sulfate for night cramps, stop taking the tablets and talk to your doctor immediately.

The following side effects have also been reported:

- 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
- 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
- problems with blood clotting
- aggravation of myasthenia gravis
- Asthma, fever.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. 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](http://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**

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

The tablets should be stored below 25°C in the package or container supplied. Do not transfer them to another container.

Do not use this medicine after the expiry date which is stated on the outer packaging. 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 Sulfate Tablets contain:**

- The active substance is quinine sulfate.
- The other ingredients are alginic acid (E400), magnesium stearate (E572), maize starch, sucrose, talc (E553), gelatin and titanium dioxide (E171). The printing ink contains shellac (E904), black iron oxide (E172) and propylene glycol (E1520). The tablet polish contains shellac (E904), carnauba wax (E903) and white beeswax (E901).

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

- The Quinine Sulfate 200 mg Tablets are white, biconvex, sugar-coated tablets. They are plain on one side, marked 200 over 1205 on the reverse.
- The product is available in pack sizes of 7, 10, 14, 21, 28, 30, 56, 60, 84, 90, 100, 110, 112, 120, 150, 160, 168, and 500 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### Manufacturer

TEVA UK Limited, Eastbourne, BN22 9AG

#### Marketing Authorisation holder

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

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