PATIENT INFORMATION LEAFLET

QUININE BISULPHATE 300mg TABLETS

Please read this leaflet carefully before you start to take this medicine.

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

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1. WHAT YOUR MEDICINE IS AND WHAT IT IS USED FOR

The name of your medicine is Quinine Bisulphate 300mg Tablets.

Quinine Bisulphate 300mg Tablets contain the anti-malarial drug quinine bisulphate and are used to treat 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 bisulphate has a relaxant action on skeletal muscle. Your doctor may have prescribed this medicine for the treatment of night leg cramps.

2. BEFORE YOU TAKE YOUR MEDICINE

Do not use your medicine if you:

- are allergic to quinine or any of its salts or any of the other ingredients in the tablet (Please note: quinine is an ingredient in some tonic waters and other beverages.)
- have problems with your eye sight (due to inflammation of the optic nerve)
- have blood in the urine
- suffer from myasthenia gravis (condition causing muscle weakness)
- suffer from ringing in the ears

Take special care with your medicine
You should let your doctor know and ask their advice, if you suffer from, or have ever had:

- irregular heart beat or other heart problems
- an enzyme deficiency called glucose-6-phosphate dehydrogenase deficiency (as this can cause anaemia)

Taking other medication
Your medicine may interfere with other medicines that you are taking. Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicine even those not prescribed, especially:

- Digoxin or Flecainide, used to treat heart conditions
- Anticoagulants, used to prevent blood clots
- Barbiturates, carbamazepine and phenytoin, used in the treatment of epilepsy
- Terfenadine used for allergic reactions
- Amantadine used to treat Parkinson’s disease or some viral infections
- Ciclosporin, used following an organ transplant
- Moxifloxacin, or rifampicin antibiotics used to treat bacterial infections
- Ketoconazole, used in the treatment of fungal skin infections
- Drugs used to treat diabetes
- Suxamethonium used to relax muscles
- Chloroquine and mefloquine, artemether with lumefantrine for the treatment of malaria
- Pimozide and thioridazine, used to treat mental disorders such as schizophrenia
- Amiodarone, used to treat heart conditions
- Medicines, used in treating HIV infections e.g. nelfinavir
- Quinidine, used to treat abnormal heart rhythm.
- Cimetidine used to treat stomach ulcers or acid reflux and indigestion

Your doctor will advise you about this.

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

**Pregnancy and breast-feeding**
Before taking your medicine, tell your doctor if you are pregnant or trying to become pregnant. You should not take quinine bisulphate 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.

### 3. HOW TO TAKE YOUR MEDICINE

Always take your medicine exactly as your doctor has instructed you. You should check with your doctor or pharmacist, if you are unsure. Do not take more than your doctor has recommended.

**Your medicine should be taken by mouth as follows:**

**For the treatment of Malaria:**

**Adults and children over 11 years, including the elderly:**
The usual dose is 600mg (2 x 300mg tablets) three times daily for 7 to 10 days.

**Children aged 11 years and under:**
10mg/kg every eight hours for 7 days

**For the treatment of Night Cramps:**

**Adults:**
300mg (1 tablet) at bedtime.

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

**Kidney and liver problems:**
If you have kidney or liver disease you may be given a different dose.
If you take more of your medicine than you should
If you take too many tablets tell your doctor or hospital casualty department straight away. Take your medicine with you.

If you forget to take your medicine
If you do forget to take a dose of your medicine at the correct time, take it as soon as you remember, then carry on as before. However, never take a double dose to make up for forgotten individual doses.

If you stop taking your medicine
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.

4. POSSIBLE SIDE EFFECTS

Tell your doctor or pharmacist 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:

- Allergic reactions – swelling of the lips, face, throat or tongue, flushing, fever, chill or sore throat, asthma or sensitivity to light
- Disturbed vision (blurred vision, changes in colour perception or field of vision, total blindness), ringing in the ears or loss of hearing and irregular heartbeats. These symptoms are normally only severe in quinine overdose
- Changes to blood cells- if you notice that you are bruising easily or have frequent nosebleeds, tell your doctor who may want to give you a blood test. These can be signs of blood or bone marrow problems
- A severe reduction in the number of white blood cells can make infections more likely or a reduction of red blood cells can make the skin pale (anaemia) and cause weakness or breathlessness.

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

- Headache, dizziness, confusion or agitation
- Feeling or being sick (nausea or vomiting), abdominal pain or diarrhoea
- Itchy skin rash
- Muscle weakness
- Low blood sugar levels
- Low blood pressure
- Kidney problems (decreased urine production or no urine, or reddish colour in the urine)

These are some of the more common side effects of quinine and are usually associated with long-term treatment with Quinine Bisulphate 300mg Tablets.

The list of side effects mentioned above is not completed. 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.
5. STORING YOUR MEDICINE

Do not use your medicine after the expiry date shown on the carton.

**KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.**

Do not store your medicine above 25°C. Store in a dry place and protect from light.

Store in the original package and do not transfer your medicine to another container.

If your doctor tells you to stop treatment, return any left over to the pharmacist. Only keep it if the doctor tells you to. 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. MORE INFORMATION

**What your medicine contains**

Quinine Bisulphate 300mg Tablets contain 300mg of the active ingredient quinine bisulphate. The other ingredients are silicon dioxide (E551), guar gum, magnesium stearate, microcrystalline cellulose, hydroxypropylmethylcellulose, ethylcellulose, polyethylene glycol and titanium dioxide (E171) beeswax and purified water.

**What your medicine looks like and contents of the pack**

Quinine Bisulphate 300mg tablets are plain white film coated tablets. These tablets are available in packs of 28 and 500. Not all pack sizes may be marketed.

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:**

Athlone Laboratories Limited, Ballymurray, Co. Roscommon, Ireland.

**Company responsible for batch release:**

Kent Pharmaceuticals Limited, Wotton Road, Ashford, Kent, TN23, 6LL, U.K.

Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

**Distributor:**

Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

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