Patient Information Leaflet

QUININE BISULFATE 300MG 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 other questions, or if there is something you do not understand, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Never give it to someone else. It may not be the right medicine for 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

In this leaflet:

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

1. What Quinine bisulfate is and what it is used for

Quinine bisulfate belongs to a group of medicines called anti-protozoal agents and they are used to treat:
- malaria
- and prevent night cramps in adults and the elderly when sleep is regularly disrupted

2. What you need to know before you take Quinine bisulfate

Do NOT take quinine bisulfate if you:
- are **allergic** (hypersensitive) to **quinine** or any of the other ingredients of this medicine (listed in section 6)
- have **haemolytic anaemia** (tiredness caused by the destruction of red blood cells)
- have blood in your **urine**
- have **tinnitus** (ringing sound in the ears)
- have **optic neuritis** (loss of vision or difficulty seeing)
- have **haemoglobinuria** (high concentration of haemoglobin in urine)
- have **myasthenia gravis** (suffer from muscle weakness)

Warnings and precautions
Talk to your doctor or pharmacist before taking these tablets if you:
- have irregular **heartbeats** or other heart problems
- suffer from **kidney or liver** problems
- have had **malaria** for a long time
- suffer from glucose-6-phosphate dehydrogenase deficiency (G6PD), this can increase the risk of the destruction of **red blood cells** during quinine therapy
- consume excessive amounts of beverages that contain quinine such as tonic water

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 bisulfate
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Tell your doctor if you are taking any of the following medicines, as special care may be required:
- warfarin (to prevent blood clots)
- chloroquine (for rheumatoid arthritis, malaria)
- cimetidine (to treat stomach ulcer)
- digoxin (for heart problems)
- amantadine (to treat Parkinsons Disease or some viral infections)
- halofantrine, mefloquine or artemether with lumefantrine or primaquine (also to treat malaria)
- flecainide, quinidine or amiodarone (to treat irregular heartbeats)
- terfenadine (for allergic reactions)
- ciclosporin (to prevent transplant rejection)
- pimozide or thioridazine (to treat some mental disorders)
- moxifloxacin or rifampicin (to treat infections)
- metformin (medicines to treat diabetes)
- suxamethonium (a muscle relaxant)
- ritonavir, indinavir (HIV medicines)
- barbiturates, phenytoin or carbamazepine (anticonvulsants)

Pregnancy and breast feeding
You should not take quinine bisulfate tablets if you are pregnant, planning to become pregnant or breast-feeding unless advised by your doctor. **Quinine bisulfate tablets should not be used for night cramps during pregnancy**.

Driving and using machines
Quinine bisulfate -tablets may affect your vision or cause vertigo (a feeling of dizziness or spinning). Make sure you are not affected before you drive or operate machinery.

Quinine bisulfate- contains sucrose
These tablets contain sucrose. If you have been told by you doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Quinine bisulfate

Always take this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Swallow the tablets with water.

For uncomplicated malaria (you may be given another medicine for malaria with or after this course of quinine**):**
- **Adults, the elderly and children over 12 years -** Two tablets every eight hours for 7 days.
- **Children under 12 years -** Equivalent of 10mg/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.

For the relief of nocturnal cramps:

- **Adults and the elderly**

300mg at bedtime.

It may take up to 4 weeks before you notice any reduction in the frequency of leg cramps.

Do not take more than the recommended dose

If you take more quinine bisulfate -than you should

If you or anyone else has taken too many tablets, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Take any remaining tablets with you to show the doctor.

Symptoms of overdose include loss of consciousness, difficulty breathing, changes in heart beat, fits, 'ringing' in the ears, loss of hearing, headache, feeling or being sick, kidney failure and changes in vision. Severe poisoning can produce convulsions, coma, permanent loss of vision, respiratory depression and death.

If you forget to take quinine bisulfate

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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, quinine bisulfate -tablets can cause side effects, although not everybody gets them.

Contact your doctor at once if the following serious side effects occur:

- **allergic reactions** –itchy skin rash, swelling of the lips, face, throat or tongue, flushing, fever, asthma or sensitivity to light
- **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 these 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

Talk to 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
- 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
- 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

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 at: www.mhra.gov.uk/yellowcard By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Quinine bisulfate

Keep all medicines out of the sight and reach of children.

- Do not take this medicine after the expiry date printed after abbreviation 'EXP' on the carton, blister pack or bottle.
- Do not store above 25˚C.
- Protect from light and moisture.
- Store in the original package (for blister packs and bottles).

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 to protect the environment.

6. Contents of the pack and other information

What quinine bisulfate- tablets contain

- The active substance is quinine bisulfate-. Each tablet contains 300mg quinine bisulfate-.
- The other ingredients are: maize starch, polyvinylpyrrolidone, talc, stearic acid, sodium starch glycollate, opaglos, sucrose and titanium dioxide.

See end of section 2 for further information on sucrose.

What quinine bisulfate- tablets look like and contents of the pack:

Quinine bisulfate- tablets are white, round, biconvex sugar coated tablets.

Pack sizes for quinine bisulfate- are "25, 28, 30, 50, 56, 100, 250, 500 and 1000 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Pharmvit Ltd, 177 Bilton Road, Perivale, Greenford, Middlesex UB6 7HQ.
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