SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

GENERIC: Quinine Sulfate Tablets BP 300 mg

BRAND NAME: Quinine Sulfate Tablets BP 300 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:

Quinine Sulfate BP …….. 300 mg

Excipients……q.s.

Colour: Titanium dioxide

3. PHARMACEUTICAL FORM:

Oral, Solid, Dosage Form – Tablets.

White coloured, film coated, bi-convex, Circular shape tablets plain on both sides.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication:

It is indicated for malaria.

4.2 Posology and method of administration:

As directed by the physician.

Method of administration: For oral administration only.

4.3 Contraindications:

Hypersensitivity to quinine or quinidine. Myasthaenia gravis haemolytic anaemia quinine resistant falciparum patients with tinnitus or optic neuritis patients who have suffered an attack of blackwater fever. Prolonged QT interval. Pregnancy.

4.4 Warning and precautions for use

Lactation. CV diseases; G6PD deficient individuals.

4.5 Drug Interactions

Rifamipicin accelerates quinine clearance cimetidine inhibits quinine metabolism quinine may enhance hypoglycaemic effect of oral ant diabetics. concurrent admin with aluminum and or magnesium containing antacids may decrease the absorption of quinine potentially fatal increases digitalis toxicity hypoprothrobinaemic effect to warfarin enhanced by quinine increased risk of convulsions with mefloquine increase risk of ventricular arrtythmias with halofantrine or other arrthythmogenic drugs e.e amiodrone ,astemizole terfenadine cisapride and pimozide.

4.6 Fertility Pregnancy & Lactation

Pregnancy

Large doses of quinine can induce abortion. Quinine may cause congenital abnormalities of the CNS and extremities. Following administration of large doses during pregnancy, phototoxicity and deafness have been reported in neonates. Quinine sulfate should not be used during pregnancy unless the benefits outweigh the risks.

Treatment of falciparium malaria: Pregnancy in a patient with malaria is not generally regarded as a contraindication to the use of quinine. As malaria infection is potentially serious during pregnancy and poses a threat to the mother and foetus, there appears to be little justification in withholding treatment in the absence of a suitable alternative.

Prophylaxis of nocturnal leg-cramps: Quinine sulfate should not be used during pregnancy to treat cramps.

Breastfeeding

Quinine sulfate is excreted in breast milk, but no problems in humans have been reported. . Infants at risk for glucose-6-phosphate dehydrogenase deficiency should not be breast-fed until this disease can be ruled out. However, quinine sulfate should not be given to nursing mothers unless the benefits outweigh the risks.

4.7 Effects on ability to drive and use machines:

Quinine may cause visual disturbances and vertigo, hence patients should be advised that if affected they should not drive or operate machinery.

4.8 Adverse Effects

Cinchonism characterized by tinnitus, impaired hearing, headache, nausea, vomiting, disturbed vision, vertigo, abdominal pain and diarrhea; urtcaria, pruritus, fever, angioedema, asthma, dyspnea, haemoglobinuria, thrombocytopenic purpura, hypogycaemia, renal failure, hypoprothrombinaemia, agranulocytosis, irritation, pain and necrosis. Potentially fatal: sinus arrest, AV block, ventricular fibrillation and sudden death especially with IV use.

4.9 Overdose

Acute intoxication can be seen after ingestion of doses of 4-12g, but a dose of 8g can prove lethal. The average fatal dose for an adult is about 8g although deaths have been reported from as little as 1.5g in an adult and 900mg in a child.

Symptoms: Quinine overdosage may lead to serious side effects including irreversible visual loss, and can be fatal.

Symptoms include vomiting, tinnitus, deafness, headache, vasodilation and visual disturbance.

Features of a significant overdose include convulsions, impairment of consciousness, respiratory depression, QT prolongation, ventricular arrhythmia, cardiogenic shock and renal failure. High doses of quinine are teratogenic and may cause miscarriage. Hypokalaemia and hypoglycaemia may also occur.

Treatment: Children (< 5 years) who have ingested any amount should be referred to hospital. Older children and adults should be referred to hospital if more than 30 mg/kg of quinine base has been taken.

Each 200 mg tablet is equivalent to 165 mg quinine base, each 300 mg tablet is equivalent to 248 mg quinine base.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

Pharmacotherpeutic group: Quinine alkaloid.

ATC Code: P01B C01.

Quinine is a cinchona alkaloid and a 4-methanolquinoline antimalarial agent which is a rapidly acting blood schizontocide with activity against Plasmodium falciparum, P vivax, P ovale and P malariae. It is active against the gametocytes of P malariae and P vivax, but not against mature gametocytes of P falciparum. Since it has no activity against exoerythrocytic forms, quinine does not produce a radical cure in vivax or ovale malarias.

<u>Pharmacodynamnic effect</u>

Quinine has effects on the motor end-plate of skeletal muscle and prolongs the refractory period. Like quinidine, quinine is a sodium channel blocker and, therefore, has local anaesthetic, and both anti- and proarrhythmic activity.

Mechanism of action

The precise mechanism of action of quinine is unclear but it may interfere with lysosome function or nucleic acid synthesis in the malaria parasite.

5.2 Pharmacokinetic properties

The pharmacokinetics of quinine are altered significantly by malaria infection, the major effects being reductions in both its apparent volume of distribution and its clearance.

Absorption:

Quinine is rapidly and almost completely absorbed from the GI tract and peak concentrations in the circulation are attained about 1-3 hours after oral administration of the sulfate.

Distribution:

Plasma protein binding is about 70% in healthy subjects and rises to 90% or more in patients with malaria.

Quinine is widely distributed throughout the body. Concentrations attained in the CSF of patients with cerebral malaria have been reported to be about 2-7% of those in the plasma.

Biotransformation:

Quinine is extensively metabolised in the liver and rapidly excreted mainly in the urine. Estimates of the proportion of unchanged quinine excreted in the urine vary from less than 5% to 20%. The pharmacokinetics of quinine are altered significantly by malaria infection, with reductions in both the apparent volume of distribution and clearance.

Elimination:

Excretion is increased in acid urine. The elimination half-life is about 11 hours in healthy subjects but may be prolonged in patients with malaria. Small amounts of quinine also appear in the bile and saliva. Quinine crosses the placenta and is excreted in the breast milk.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose, Maize Starch, Sodium Lauryl Sulfate, Gelatin, Purified Water, Purified Talc, Sodium Starch Glycolate, Crosscarmellose Sodium, Colloidal Anhydrous Silica, Magnesium Stearate, Ready Mix White (Instacoat Universal IC-U-3849).

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

36 Months from the date of Manufacture.

6.4 Special precautions for storage:

Do not store above 30°C. Protect from light.

Keep the medicine out of reach of children.

6.5 Nature and contents of container

10 x 10’s blister further packed in a carton along with insert.

7. APPLICANT
Manufactured by:

S Kant
HEALTHCARE Ltd.

1802-1805, G.I.D.C., Phase III,
Vapi - 396 195. Gujarat, INDIA.

8. NATIONAL REGISTRATION NUMBER

07577/08443/REN/2022

9. DATE OF AUTHORISATION

01/08/2022

10. DATE OF REVISION OF THE TEXT

July 2023