Quinine Sulphate Tablets USP 300mg

COMPOSITION : Each coated tablet contains:
Quinine Sulphate USP 300mg
Excipients q.s.
Colour: Approved colour used.

CLINICAL PHARMACOLOGY :
Quinine has been found to be highly active against the erythrocytic forms of Plasmodium vivax, ovale and malariae and many strains of Plasmodium falciparum (but not the gametocytes of Plasmodium falciparum). The precise mechanism of plasmodium action of the drug is not known. While the drug can inhibit certain enzymes, its effect is believed to result, in part, from its interaction with DNA.
Quinine does not prevent vivax malariae infection when administered prophylactically. It acts on the erythrocytic forms of the parasite, inhibiting parasite development in the red blood cell thus preventing or suppressing clinical symptoms. Quinine does not prevent relapses in patients with vivax or malariae malaria because it is not effective against exo-erythrocytic forms of the parasite. It is highly effective as a suppressive agent in patients with vivax or malariae malaria, in terminating acute attacks, and significantly lengthening the interval between treatment and relapse. In patients with a susceptible strain of falciparum malaria, it abolishes the acute attack and effects complete cure of the infection
In vitro studies with trophozoites of Entamoeba histolytica have demonstrated that Quinine also possesses amebicidal activity comparable to that of emetine.
Quinine is rapidly and almost completely absorbed from the gastrointestinal tract. Approximately 55% of the drug in the plasma is bound to non diffusible plasma constituents. Quinine is deposited in tissues in considerable amounts. In animals, from 200 to 700 times the plasma concentration may be found in the liver, spleen, kidney and lung; leukocytes also concentrate the drug. The brain and spinal cord, in contrast, contain only 10 to 30 times the amount present in plasma.
Quinine undergoes appreciable degradation in the body. The main metabolite is desethyl quinine. Bisdesethyl quinine, a carboxylic acid derivative and other uncharacterized metabolites are found in small amounts. Slightly more than half of the urinary drug products can be accounted for as unchanged Quinine and about one fourth is desethyl Quinine. Excretion is quite slow, but can be increased by acidification of urine.

CONTRA-INDICATIONS :
The presence of retinal or visual field changes either attributable to 4 - aminoquinoline compounds or to any other etiology, and in patients with known hypersensitivity to 4 – aminoquinoline compounds. However, in the treatment of acute attacks of malaria caused by susceptible strains of plasmodia, the physician may elect to use this drug after carefully weighing the possible benefits and risks to the patient.

PRECAUTIONS :
In recent years it has been found that certain strains of P.falciparum have become resistant to 4 – aminoquinoline compounds (including Quinine and hydroxyl quinine) as shown by the fact that normally adequate doses have failed to prevent or cure clinical malaria or parasitemia. Treatment with quinine or other specific forms of therapy is therefore advised for patients infected with a resistant strain of parasites.
Irreversible retinal damage has been observed in some patients who had received long term or high dosage 4 – aminoquinoline therapy. Retinopathy has been reported to be dose-related. When prolonged therapy with any antimalaria compound is contemplated, initial (base line) and periodic ophthalmologic examinations (including visual acuity, expert slit lamp, funduscopic, and visual field tests) should be performed.
Use of Quinine in patients with psoriasis may precipitate a severe attack of psoriasis. When used in patients with porphyria, the condition may be exacerbated. The drug should not be used in these conditions unless in the judgment of the physician the benefit to the patient outweighs the possible hazard.
In patients with pre-existing auditory damage, Quinine should be administered with caution. In case of any defect in hearing, Quinine should be immediately discontinued, and the patient closely observed. Patients with a history of epilepsy should be advised about the risk of Quinine provoking seizures.

PREGNANCY :
Usage of this drug during pregnancy should be avoided except in the suppression or treatment of malaria when in the judgment of the physician the benefit outweighs the possible hazard. It should be noted that radioactively tagged Quinine administered i.v. to pregnant pigmented CBA mice passed rapidly across the placenta, accumulated selectively in the melanin structures of the fetal eyes and was retained in the ocular tissues for 5 months after the drug had been eliminated from the rest of the body.

LACTATION :
be made whether to discontinue breast-feeding or to discontinue the drug, taking into account the importance of the therapy to the mother.
Since the drug is known to concentrate in the liver, it should be used with caution in patients with hepatic disease or alcoholism or in conjunction with known Hepatotoxic drugs.
Complete blood cell count should be made periodically if patients are given prolonged therapy. If any severe blood disorder appears which is not attributable to the disease under treatment, discontinuance of the drug should be considered. The drug should be administered with caution to patients having G-6-PD (glucose-6-phosphate dehydrogenase) deficiency.
Drug interactions: Antacids and kaolin can reduce the absorption of Quinine. An interval of at least 4 hours between intake of these agents and Quinine should be observed.
Cyclosporine serum level has been reported to suddenly increase following the ingestion of Quinine. Close monitoring of serum cyclosporine level is recommended following ingestion of Quinine.
Quinine should be discontinued if necessary.
Caution should be observed in prescribing Quinine concomitantly with any known Hepatotoxic agent (see precautions).

ADVERSE REACTIONS :
Quinine is generally well tolerated when given in antimalaria doses. Adverse effects are rare.
Ocular : With long-term therapy, particularly if high doses are used, retinopathy may occur. This is generally irreversible and sometimes progressive. Rarely, it may be delayed.
Retinal changes include narrowing of the arterioles, macular lesions such as areas of oedema, atrophy and abnormal pigmentation with loss of foveal reflex, pallor of the optic disk, optic atrophy and patchy retinal pigmentation.Initially patients with retinal changes may be asymptomatic, or they may complain of nyctalopia and scotomatous vision with paracentral, paracentral ring types and typically temporal scotomas.
Rarely, scotomatous vision may occur without observable retinal changes.
Reversible comeal changes may develop, including transient oedema or opaque deposits in the epithelium. These changes may be asymptomatic or cause visual haloes, focusing difficulties or blurred vision.
Transient and reversible blurring of vision or difficulty of focusing or accommodation may also occur.
Cardiovascular : Rarely, electrocardiographic changes, particularly inversion or depression of the T-wave with widening of the QRS complex, have been noted.
Hypotension has also been noted in case of high doses.
There have been rare reports of cardiomyopathy.
Neuromuscular: Skeletal muscle myopathy leading to progressive weakness and atrophy of proximal muscle groups has been noted . Myopathy is reversible after discontinuation of Quinine, but recovery may take many months.
Associated mild sensory changes, depression of tendon reflexes and abnormal nerve conduction studies suggesting an associated peripheral neuropathy have also been observed.
There have been rare reports of myasthenia gravis like signs and symptoms.

HEMATOLOGICAL :
Blood dyscrasias are rare and include aplastic anaemia, reversible agranulocytosis, thrombocytopenia and neutropenia.
Quinine may exacerbate porphyria.
Patients with G-6-PD deficiency may present with severe haemolysis in case of treatment with Quinine.

STORAGE : Store in a cool, dry & dark place.

KEEP ALL MEDICINE OUT OF THE REACH OF CHILDREN.

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