HCQ™ 200

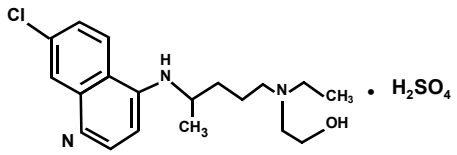
(Hydroxychloroquine Sulfate Tablets USP)

Tablets 200mg

DESCRIPTION

HCQ 200 (Hydroxychloroquine sulfate) is a 4-aminoquinoline mainly used in the treatment of rheumatoid arthritis, systemic and discoid lupus erythematosus. Hydroxychloroquine sulfate is considered a disease modifying anti-rheumatic drug (DMARD) because it not only can decrease the pain and swelling of arthritis but may also prevent joint damage and reduce the risk of long-term disability.

Chemically hydroxychloroquine sulfate is (±) 2-[[4-[(7-Chloro-4- quinolyl) amino] pentyl] ethylamino] ethanol sulfate. The molecular formula is $C_{18}H_{26}ClN_3O$. H_2SO_4 and the structural formula is:



Hydroxychloroquine Sulfate

QUALITATIVE & QUANTITATIVE COMPOSITION

HCQ 200 (Hydroxychloroquine sulfate) is available for oral administration as:

HCQ 200 Tablets
Each film-coated tablet contains:
Hydroxychloroquine sulfate USP….200mg

CLINICAL PHARMACOLOGY

Mechanism of Action

Hydroxychloroquine exerts a beneficial effect in lupus erythematosus (chronic discoid or systemic) and acute or chronic rheumatoid arthritis. The precise mechanism of action is not known.

Pharmacokinetics

Following oral administration, hydroxychloroquine is rapidly and almost completely absorbed. The mean time to peak plasma concentration is 1.83 hours. The mean plasma elimination half-life varied, depending on the post-administration period. The parent compound and metabolites are widely distributed in the body and elimination is mainly via the urine.

THERAPEUTIC INDICATIONS

HCQ 200 (Hydroxychloroquine sulfate) is indicated for the treatment of:

- Active rheumatoid arthritis (including juvenile idiopathic arthritis).
- Systemic and discoid lupus erythematosus.
- Dermatological conditions caused or aggravated by sunlight.

DOSAGE AND ADMINISTRATION

Active Rheumatoid Arthritis & Lupus Erythematosus

Active Rheumatoid Arthritis

Adults: A suitable initial dose of HCQ 200 (Hydroxychloroquine sulfate) is 400mg to 600mg (2 or 3 tablets) daily, preferably taken at meal times. Four to twelve weeks therapy is required before the effect of treatment can be evaluated.

Lupus Erythematosus

The dose of HCQ 200 (Hydroxychloroquine sulfate) depends on the severity of the disease and the patient's response to treatment.

Adults:

An initial recommended dose of HCQ 200 (Hydroxychloroquine sulfate) is 400-800mg daily. This level can be maintained for several weeks and then reduced to a maintenance dose.

Maintenance dose:

Doses are reduced to the minimum effective dose for maintenance that is 200-400mg daily but should not exceed 6.5mg/kg body weight daily (or 400mg daily whichever is smaller). To avoid excessive dosage in obese patients, special care is needed to calculate the dosage on the basis of lean body weight.

Children:

The minimum effective dose should be used upto a maximum of 6.5mg/kg body weight daily (or 400mg daily whichever is smaller).

Dermatological Conditions

HCQ 200 (Hydroxychloroquine sulfate) is also used in similar doses as in rheumatoid arthritis but the treatment should only be given during periods of maximum exposure to light.

ADVERSE REACTIONS

The side-effects of hydroxychloroquine includes gastro-intestinal disturbances, headache and skin reactions (rashes, pruritus); those occurring less frequently include convulsions, visual changes, keratopathy, ototoxicity, hair depigmentation, hair loss, and discoloration of skin, nails, and mucous membranes.

In rare cases, hydroxychloroquine has caused visual changes or loss of vision. Such vision problems are more likely to occur in individuals taking high doses for many years. At the current recommended dose, development of visual problems while taking this medication is extremely unusual.

Side-effects that occur rarely include blood disorders (including thrombocytopenia, agranulocytosis and aplastic anemia), mental changes (including emotional disturbances and psychosis), myopathy, (including cardiomyopathy and neuromyopathy), acute generalized exanthematous pustulosis, exfoliative dermatitis, Stevens-Johnson syndrome, photosensitivity and hepatic damage, angioedema has also been reported.

CONTRAINDICATIONS

Hydroxychloroquine is contraindicated in:

- Patients with known hypersensitivity to 4-aminoquinoline compounds.
- Patients with pre-existing maculopathy of the eye.
- Long-term therapy in children.
- Children under 6 years of age.

PRECAUTIONS

- The drug should be used with caution in neurological disorders (especially in those with a history of epilepsy).
- In the treatment of rheumatoid arthritis, if objective improvement does not occur within six months, the drug should be discontinued.
- Use of hydroxychloroquine in patients with psoriasis may

precipitate a severe attack of psoriasis. The preparation should not be used in these conditions unless in the judgment of the physician the benefit to the patient outweighs the possible hazard.

- Periodic blood cell counts should be made if patients are given prolonged therapy. If any severe blood disorder appears which is not attributable to the disease under treatment, discontinuation of the drug should be considered.
- The drug should be administered with caution in patients having G-6-PD (glucose-6- phosphate dehydrogenase) deficiency.
- Hydroxychloroquine may exacerbate psoriasis and aggravate myasthenia gravis.
- Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.
- All patients on long-term therapy should undergo periodic examination of skeletal muscle function and tendon reflexes. If weakness occurs, the drug should be withdrawn.
- Dermatologic reactions to hydroxychloroquine may occur and, therefore, proper care should be exercised when it is administered to any patient receiving a drug with a significant tendency to produce dermatitis.
- Small children are particularly sensitive to the toxic effects of 4-aminoquinolines; therefore patients should be warned to keep hydroxychloroquine out of the reach of children.
- In severe gastro-intestinal disorders, in acute porphyria and in the elderly.

Pediatric use
Safe use of the drug in the treatment of juvenile rheumatoid arthritis has not been established.

Pregnancy
Hydroxychloroquine crosses the placenta. Data are limited regarding its use during pregnancy. Therefore, hydroxychloroquine should not be used in pregnancy.

Nursing Mothers
Careful consideration should be given to using hydroxychloroquine during lactation, since it has been known to be excreted in small amounts in human breast milk and it is known that infants are extremely sensitive to the toxic effects of 4-aminoquinones.

Drug Interactions

- Alfa and Beta Agalsidase - Laronidase	Hydroxychloroquine possibly inhibits effect of alfa and beta agalsidase and also laronidase.
- Amiodarone - Droperidol - Moxifloxacin	Increased risk of ventricular arrhythmias when hydroxychloroquine given in combinations avoid its concomitant use.
- Antacids - Kaolin - Lanthanum	Absorption of hydroxychloroquine reduced. Incase of lanthanum it should be given at least 2 hours apart.
- Antiepileptic - Mefloquine	Possible incresed risk of convulsions when hydrochloroquine given in combination.
- Ciclosporin - Digoxin	Hydroxychloroquine increases plasma concentration (increased risk of toxicity).
- Cimetidine	Metabolism of hydroxychloroquine inhibited by Cimetidine. (increased plasma concentration)
- Neostigmine - Pyridostigmine	Hydroxychloroquine have potential to increase symptoms of myasthenia gravis and thus diminish effects of neostigmine and pyridostigmine.

OVERDOSAGE
Overdosage with the 4-aminoquinolines is dangerous particulary in infants, as little as 1-2 grams having proved fatal.
Symptoms
The 4-aminoquinoline compounds are very rapidly and completely absorbed following ingestion and in accidental overdosage toxic symptoms may occur within 30 minutes. These consist of headache, drowsiness, visual disturbances, cardiovascular collapse, hypokalemia and convulsions, followed by sudden and early respiratory and cardiac arrest.

Management
Management is symptomatic and must be prompt with immediate evacuation of the stomach by emesis, or gastric lavage until the stomach is completely emptied. If finely powdered activated charcoal is introduced by the stomach tube, after lavage and within 30 minutes after ingestion of the tablets, it may inhibit further intestinal absorption of the drug. To be effective, the dose of activated charcoal should be at least five times the estimated dose of ingested hydroxychloroquine. Convulsions, if present, should be controlled before attempting gastric lavage.

Consideration should be given to administering diazepam parenterally since studies have reported it beneficial in reversing chloroquine cardiotoxicity.

STORAGE
Store below 30°C.
Protect from sunlight & moisture.
The expiration date refers to the product correctly stored at the required conditions.

HOW SUPPLIED
HCQ 200 (Hydroxychloroquine sulfate) Tablets 200mg are available in blister pack of 30's.

Keep out of reach of children.

To be sold on prescription of a registered medical practitioner only.

Please read the contents carefully before use.
This package insert is continually updated from time to time.

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