

Material Safety data sheet

HYDROXYCHLOROQUINE SULFATE TABLETS, USP

Strength: 200mg.

Pack Size: 100/500 Tablets per bottle

Revision No.: 00

EMERGENCY OVERVIEW

HYDROXYCHLOROQUINE SULFATE TABLETS contain Hydroxychloroquine Sulfate and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

Section 1. Identification of the substance

Identification of the product

Product name:	HYDROXYCHLOROQUINE SULFATE TABLETS
Chemical Formula:	C ₁₈ H ₂₆ Cl N ₃ O ₂ SO ₄
Chemical Name:	2-[[4-[(7-Chloro-4-quinolyloxy) amino] pentyl] ethylamino] ethanol sulfate (1:1).
Therapeutic Category	Antimalarial and in treatment of <i>Lupus erythematosus</i> <i>Rheumatoid arthritis</i>

Manufacturer / supplier identification

Company:	Cadila Healthcare Ltd. Ahmedabad, India
Contact for information:	Tel.: +91 79 6868100 Fax: +91 79 3750319
Emergency telephone No.	Tel.: +91 79 6868100

Section 2. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component :		
Hydroxychloroquine sulfate	Not Found	747-36-4
Inactive Ingredients :		
Dibasic calcium phosphate dihydrate	Not Found	7789-77-7
Magnesium stearate	Not Found	557-04-0
Pregelatinized starch	Not Found	119-58-4
Polyethylene glycol	Not Found	25322-68-3
Polyvinyl alcohol	Not Found	9002-89-5
Starch	Not Found	119-58-4
Talc	Not Found	14807-96-6
Titanium dioxide	Not Found	13463-67-7

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Section 3. Health Hazards Information

Dose and Administration One tablet of 200 mg of hydroxychloroquine sulfate is equivalent to 155 mg base.

Malaria: Suppression

In adults, 400 mg (=310 mg base) on exactly the same day of each week. *In infants and children*, the weekly suppressive dosage is 5 mg, calculated as base, per kg of body weight, but should not exceed the adult dose regardless of weight.

Treatment of the acute attack

In adults, an initial dose of 800 mg (=620 mg base) followed by 400 mg (=310 mg base) in six to eight hours and 400 mg (=310 mg base) on each of two consecutive days (total 2 g hydroxychloroquine sulfate or 1.55 g base).

Adverse Effects

CNS Reactions: Irritability, nervousness, emotional changes, nightmares, psychosis, headache, dizziness, vertigo, tinnitus, nystagmus, nerve deafness, convulsions, and ataxia.

Neuromuscular Reactions: Skeletal muscle palsies or skeletal muscle myopathy or neuromyopathy and atrophy of proximal muscle.

Ocular Reactions:

- *Ciliary body:* Blurred vision.
- *Cornea:* Transient edema, punctate to lineal opacities, decreased corneal sensitivity.
- *Retina: Macula:* Edema, atrophy, abnormal pigmentation, loss of foveal reflex.
- *Visual field defects:* Pericentral or paracentral scotoma, central scotoma with decreased visual acuity, rarely field constriction, abnormal color vision.

Dermatologic Reactions: Bleaching of hair, alopecia, pruritus, skin and mucosal pigmentation.

Hematologic Reactions: Various blood dyscrasias such as aplastic anemia, agranulocytosis, leukopenia, anemia, thrombocytopenia (hemolysis in individuals with glucose-6-phosphate dehydrogenase (G-6-PD) deficiency).

Gastrointestinal Reactions: Anorexia, nausea, vomiting, diarrhea, and abdominal cramps. Isolated cases of abnormal liver function and fulminant hepatic failure.

Allergic Reactions: Urticaria, angioedema and bronchospasm have been reported.

Over Dose Effect

The 4-aminoquinoline compounds are very rapidly and completely absorbed after ingestion, and in accidental overdosage, or rarely with lower doses in hypersensitive patients, toxic symptoms may occur within 30 minutes.

Medical Conditions

These consist of headache, drowsiness, visual disturbances, cardiovascular collapse, and convulsions, followed by sudden and early respiratory and cardiac arrest. The electrocardiogram may reveal atrial standstill, nodal rhythm, prolonged intraventricular conduction time, and progressive bradycardia leading to ventricular fibrillation and/or arrest.

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Contraindications	Use of this drug is contraindicated (1) in the presence of retinal or visual field changes attributable to any 4-aminoquinoline compound, (2) in patients with known hypersensitivity to 4-aminoquinoline compounds, and (3) for long-term therapy in children.
Pregnancy Comments	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 chloroquine administered intravenously to pregnant, pigmented CBA mice passed rapidly across the placenta. It accumulated selectively in the melanin structures of the fetal eyes and was retained in the ocular tissues for five months after the drug had been eliminated from the rest of the body.
Pregnancy Category	-

Section 4. First aid measures

General	Remove from exposure. Remove contaminated Clothing. Person developing serious hypersensitivity reaction must receive medical attention
Overdose Treatment	Treatment is symptomatic and must be prompt with immediate evacuation of the stomach by emesis (at home, before transportation to the hospital) or gastric lavage until the stomach is completely emptied. Convulsions due to cerebral stimulation, cautious administration of an ultrashort-acting barbiturate may be tried but, if due to anoxia, it should be corrected by oxygen administration, artificial respiration or, in shock with hypotension, by vasopressor therapy.

Section 5. Fire – fighting measures

Flash point	Not Found	Upper Flammable Limit:	Not Found
Auto-Ignition Temperature:	Not Found	Lower Flammable Limit:	Not Found
Extinguishing Media	Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.	Fire and Explosion Hazard	This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with the dry material to dissipate the potential build up of static electricity.
Fire Fighting Procedure	As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing.		

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Section 6. Storage / Spill / Disposal Measures

Storage	Store at 20°-25°C (68°-77°F) Dispense in a tight, light-resistant container.
Spill Response	Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage using high efficiency vacuum cleaner. Avoid breathing dust.
Disposal	Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 7. Exposure controls and personal protection

Respiratory Protection	Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.
Skin Protection	Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.
Eye protection	Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.
Protective Clothing	Protective clothing is not normally necessary, however it is good practice to use apron.

Section 8. Physical and chemical properties

Appearance	Hydroxychloroquine Sulfate Tablets, USP contain 200 mg of hydroxychloroquine sulfate, are white to off-white, capsule-shaped, biconvex, film-coated tablets debossed with "ZC38" on one side and plain on other side.		
Solubility in water	No Data Available	Odour	Odourless
Boiling point	No Data Available	Melting Point	No Data Available
Evaporation rate	No Data Available	Vapour density	No Data Available
Reactivity in water	No Data Available	Evaporation rate	No Data Available
Percentage Volatile by volume	No Data Available	Specific gravity	No Data Available
Vapour pressure	No Data Available		
Other information	Hydroxychloroquine sulfate is an odorless, white or practically white crystalline powder, freely soluble in water; practically insoluble in alcohol, in chloroform, and in ether.		

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Section 9. Physical Hazards

Condition to avoid	Avoid exposure to extreme heat, light and moisture.	Stable	Stable under normal ambient and anticipated storage and handling conditions.
Decomposition Products	No Data Available	Hazardous Reaction	No data available.
Incompatibilities	No data available.		

Section 10. Toxicological information

General	Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.
Target organ	Eye contact, Skin contact and inhalation is not great risk as this product is tablet.
other	-

Section 11. Ecological information

No data available on Ecotoxicity

Section 12. Other information

None

Date of issue: 15/10/2007

Supersedes edition of: New Edition

The information contained herein is based on the state of our knowledge. It Characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.