SAFETY DATA SHEETS

This SDS packet was issued with item:

078944983

N/A

Zydus

Safety Data Sheet
HYDROXYCHLOROQUINE SULFATE TABLETS, USP

Strength: 200mg. **Pack Size:** 100/500 Tablets per bottle **Revision No.:** 02

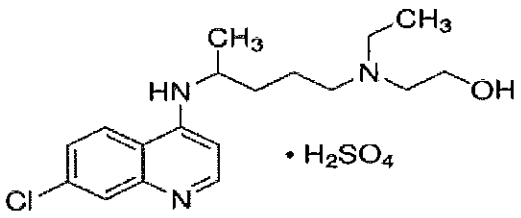
EMERGENCY OVERVIEW

Each Hydroxychloroquine sulfate tablets USP intended for oral administration contains 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

Identification of the product

Product name:	**Hydroxychloroquine sulfate Tablets, USP**
Chemical Formula:	$C_{18}H_{26}Cl\,N_3OH_2SO_4$
Chemical Name:	2-[[4-[(7-Chloro-4-quinolyl)amino] pentyl] ethylamino] ethanol sulfate (1:1).



Manufacturer / supplier identification

Company:	**Cadila Healthcare Ltd. Ahmedabad, India**
Address:	Sarkhej – Bavla. N.H. 8A, Moraiya. Tal. Sanand. Dist. Ahmedabad – 382210. State: Gujarat. India
Contact for information:	Tel.: +91 79 6868100 Fax: +91 79 3750319
Emergency Telephone No.	Tel.: +91 79 6868100
Recommended use / Therapeutic Category	Antimalarial and in treatment of Lupus erythematosus Rheumatoid arthritis.
Restriction on Use / 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.

Section 2. Hazard(s) 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 hydroxychloroquiue 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.

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 3. 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

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.

Section 6. Accidental Release Measures

Spill Response Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

Section 7. Handling and Storage

Storage Store at 20° to 25°C (68° to 77°F).
Dispense in a tight, light-resistant container.

Incompatibilities: No Data availables.

Section 8. Exposnre controls / 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.
Engineering Control	Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Section 9, 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
% 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.

Section 10. Stability and Reactivity

Condition to avoid	Avoid exposure to extreme heat, light and moisture.	**Stable**	Stable under normal ambient and anticipated storage and handling conditions.

Strength: 200mg. **Pack Size:** 100/500 Tablets per bottle **Revision No.:** 02

Decomposition Products	No Data Available	**Hazardous Reaction**	No data available.

Incompatibilities: No Data Available.

Section 11. 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 Not applicable.

Section 12. Ecological information

Do not allow product to enter drinking water supplies, waste water or soil

Section 13. Disposal Consideration

Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).

Section 15. Regulatory Information

Generic Medicine. Approved by USFDA & the ANDA Number is 040657

Section 16. Other information

None

Date of issue: 28/05/2015 **Supersedes edition of:** 01

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.