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: C18H26ClN3O2S
Chemical Name: 2-[[4-[(7-Chloro-4-quinolyl) amino] pentyl] ethylamino] ethanol sulfate (1:1).
Therapeutic Category: Antimalarial and in treatment of Lupus erythematosus Rheumatoid arthritis

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
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**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Flash point</strong></td>
<td>Not Found</td>
</tr>
<tr>
<td><strong>Auto-Ignition Temperature:</strong></td>
<td>Not Found</td>
</tr>
<tr>
<td><strong>Extinguishing Media</strong></td>
<td>Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.</td>
</tr>
<tr>
<td><strong>Upper Flammable Limit:</strong></td>
<td>Not Found</td>
</tr>
<tr>
<td><strong>Lower Flammable Limit:</strong></td>
<td>Not Found</td>
</tr>
<tr>
<td><strong>Fire and Explosion Hazard</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Fire Fighting Procedure</strong></td>
<td>As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing.</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Condition to avoid</th>
<th>Stable</th>
<th>Decomposition Products</th>
<th>Hazardous Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avoid exposure to extreme heat, light and moisture.</td>
<td>Stable under normal ambient and anticipated storage and handling conditions.</td>
<td>No Data Available</td>
<td>No data available.</td>
</tr>
</tbody>
</table>

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.

Section 11. Ecological information

No data available on Ecotoxicity

Section 12. Other information

None


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.