

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

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Material	Quinine Sulfate Capsules USP 324 mg
Manufacturer	Lupin Limited Goa - 403722 India
Distributor	Lupin Pharmaceuticals, Inc. 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221

Section 2: Hazard(s) Identification

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Fire and Explosion	Expected to be non-combustible.
Health	Quinine sulfate is contraindicated in patients with the following: <ul style="list-style-type: none">• Prolonged QT interval. One case of a fatal ventricular arrhythmia was reported in an elderly patient with a prolonged QT interval at baseline, who received quinine sulfate intravenously for <i>P. falciparum</i> malaria.• Glucose-6-phosphate dehydrogenase (G6PD) deficiency.• Hemolysis can occur in patients with G6PD deficiency receiving quinine.• Known hypersensitivity reactions to quinine.• These include, but are not limited to, the following.• Thrombocytopenia.• Idiopathic thrombocytopenia purpura (ITP) and Thrombotic thrombocytopenic purpura (TTP).• Hemolytic uremic syndrome (HUS).• Blackwater fever (acute intravascular hemolysis, hemoglobinuria, and hemoglobinemia).• Known hypersensitivity to mefloquine or quinidine: cross-sensitivity to quinine has been documented.• Myasthenia gravis. Quinine has neuromuscular blocking activity, and may exacerbate muscle weakness.• Optic neuritis. Quinine may exacerbate active optic neuritis.

Environment

No information is available about the potential of this product to produce adverse environmental effects.

Section 3: Composition/Information on Ingredients

Section 3, Composition/information on ingredients**Ingredients****CAS**

Quinine Sulfate USP

6119-70-6

Section 4: First-Aid Measures

Section 4, First-aid measures**Ingestion**

If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention.

Inhalation

Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.

Skin Contact

Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs.

Eye Contact

Flush eyes with plenty of water. Get medical attention.

NOTES TO HEALTH PROFESSIONALS**Medical Treatment**

Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.

OVERDOSAGE

Quinine overdose can be associated with serious complications, including visual impairment, hypoglycemia, cardiac arrhythmias, and death. Visual impairment can range from blurred vision and defective color perception, to visual field constriction and permanent blindness. Cinchonism occurs in virtually all patients with quinine overdose. Symptoms range from headache, nausea, vomiting, abdominal pain, diarrhea, tinnitus, vertigo, hearing impairment, sweating, flushing, and blurred vision, to deafness, blindness, serious cardiac arrhythmias, hypotension, and circulatory collapse. Central nervous system toxicity (drowsiness, disturbances of consciousness, ataxia, convulsions, respiratory depression and coma) has also been reported with quinine overdose, as well as pulmonary edema and adult respiratory distress syndrome.

Most toxic reactions are dose-related; however, some reactions may be idiosyncratic because of the variable sensitivity of patients to the toxic effects of quinine. A lethal dose of quinine has not been clearly defined, but fatalities have been reported after the ingestion of 2 to 8 grams in adults.

Quinine, like quinidine, has Class I antiarrhythmic properties. The cardiotoxicity of quinine is due to its negative inotropic action, and to its effect on cardiac conduction, resulting in decreased rates of depolarization and conduction, and increased action potential and effective refractory period. ECG changes observed with quinine overdose include sinus tachycardia, PR prolongation, T wave inversion, bundle branch block, an increased QT interval, and a widening of the QRS complex. Quinine's alpha-blocking properties may result in hypotension and further exacerbate myocardial depression by decreasing coronary perfusion. Quinine overdose has been also associated with hypotension, cardiogenic shock, and circulatory collapse, ventricular arrhythmias, including ventricular tachycardia, ventricular fibrillation, idioventricular rhythm, and torsades de pointes, as well as bradycardia, and atrioventricular block.

Quinine is rapidly absorbed, and attempts to remove residual quinine sulfate from the stomach by gastric lavage may not be effective. Multiple-dose activated charcoal has been shown to decrease plasma quinine concentrations.

Forced acid diuresis, hemodialysis, charcoal column hemoperfusion, and plasma exchange were not found to be effective in significantly increasing quinine elimination in a series of 16 patients.

Section 5: Fire-Fighting Measures

Section 5, Fire-fighting measures

Fire and Explosion Hazards

Assume that this product is capable of sustaining combustion.

Extinguishing Media

Water spray, carbon dioxide, dry chemical powder or appropriate foam.

Special Firefighting Procedures

For single units (packages): No special requirements needed.

For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters.

Hazardous Combustion Products

Hazardous combustion or decomposition products are expected when the product is exposed to fire.

Section 6: Accidental Release Measures

Section 6, Accidental release measures

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways sewers, or surface drainage systems.
Clean-up Methods	Collect and place it in a suitable, properly labeled container for recovery or disposal.

Section 7: Handling and Storage

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Handling	No special control measures required for the normal handling of this product.
Storage	Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature]. Dispense in a tight container as defined in the USP.

Section 8: Exposure Controls/Personal Protection

Section 8, Exposure controls/personal protection

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

Section 9: Physical and Chemical Properties

Section 9, Physical and chemical properties

Physical Form	Quinine sulfate capsules USP, 324 mg are available as size "0" capsules with clear transparent cap and clear transparent body imprinted with "LU" on cap and "Y51" on body in black ink, containing white to off white powder:
	Bottles of 30 NDC 68180-560-06
	Bottles of 100 NDC 68180-560-01
	Bottles of 500 NDC 68180-560-02
	Bottles of 1000 NDC 68180-560-03

Section 10: Stability and Reactivity

Section 10, Stability and reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Section 11, Toxicological information

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Carcinogenicity studies of quinine have not been conducted.

Mutagenesis

Genotoxicity studies of quinine were positive in the Ames bacterial mutation assay with metabolic activation and in the sister chromatid exchange assay in mice. The sex-linked recessive lethal test performed in *Drosophila*, the in vivo mouse micronucleus assay, and the chromosomal aberration assay in mice and Chinese hamsters were negative.

Impairment of Fertility

Published studies indicate that quinine produces testicular toxicity in mice at a single intraperitoneal dose of 300 mg/kg corresponding to a dose of approximately 0.75 times the maximum recommended human dose (MRHD; 32 mg/kg/day) and in rats at an intramuscular dose of 10 mg/kg/day, 5 days/week, for 8 weeks corresponding to a daily dose of approximately 0.05 times the MRHD based on body surface area (BSA) comparisons. The findings include atrophy or degeneration of the seminiferous tubules, decreased sperm count and motility, and decreased testosterone levels in the serum and testes. There was no effect on testes weight in studies of oral doses of up to 500 mg/kg/day in mice and 700 mg/kg/day in rats (approximately 1.2 and 3.5 times the MRHD respectively based on BSA comparisons). In a published study in 5 men receiving 600 mg of quinine TID for one week, sperm motility was decreased and percent sperm with abnormal morphology was increased; sperm count and serum testosterone were unaffected.

Section 12: Ecological Information

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No relevant studies identified.

Section 13: Disposal Considerations

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Incinerate in an approved facility. Follow all federal state and local environmental regulations.

Section 14: Transport Information

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IATA/ICAO - Not Regulated

IATA Proper shipping Name	:	N/A
IATA UN/ID No	:	N/A
IATA Hazard Class	:	N/A
IATA Packaging Group	:	N/A
IATA Label	:	N/A

IMDG - Not Regulated

IMDG Proper shipping Name	:	N/A
IMDG UN/ID No	:	N/A
IMDG Hazard Class	:	N/A
IMDG Flash Point	:	N/A
IMDG Label	:	N/A

DOT - Not Regulated

DOT Proper shipping Name	:	N/A
DOT UN/ID No	:	N/A
DOT Hazard Class	:	N/A
DOT Flash Point	:	N/A
DOT Packing Group	:	N/A
DOT Label	:	N/A

Section 15: Regulatory Information

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This Section Contains Information relevant to compliance with other Federal and/or state laws.

Section 16: Other Information

Section 16, Other information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Lupin shall not be held liable for any damage resulting from handling or from contact with the above product. Lupin reserves the right to revise this MSDS.