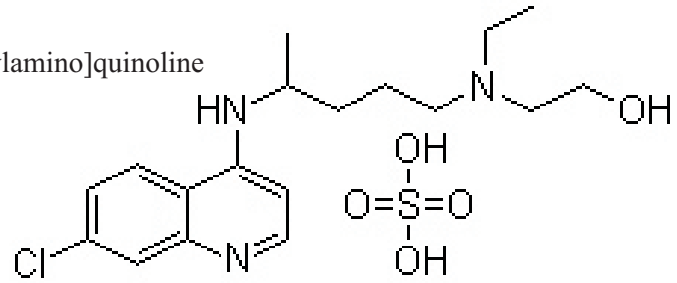
Taj Pharmaceuticals Ltd.
Hydroxychloroquine sulphate
CAS No. : 747-36-4

Synonyms

7-Chloro-4-[4-[ethyl-(2-hydroxyethyl)amino]-1-methylbutylamino]quinoline

Hydroxychloroquine sulfate, 7-Chloro-4-[4-[ethyl-(2-hydroxyethyl)amino]-1-methylbutylamino]quinoline,



CAS No: 747-36-4
Molecular Formula C18H26ClN3O.H2SO4
Molecular Weight 433.95

Hydroxychloroquine is classified as an anti-malarial medication, and is one of a number of drugs which have been used for many years in the treatment of malaria. It is useful in treating systemic lupus erythematosus as well as rheumatoid arthritis and Sjogren's Syndrome.

DOSAGE

The usual adult dose for treating malaria is 800 mg initially, followed by 400 mg 6 hours later then 400 mg on days 2 and 3. The dose for malaria prevention is 400 mg every week starting 1 or 2 weeks before exposure and for 4 weeks after leaving the high risk area.

The recommended adult dose for rheumatoid arthritis is 400-600 mg daily for 4-12 weeks followed by 200-400 mg daily.

Systemic lupus erythematosus is treated with 400 mg once or twice daily for several weeks then 200-400 mg daily. Hydroxychloroquine should be taken with food or milk in order to reduce stomach upset.

Hydroxychloroquine comes as a tablet to take by mouth. For prevention of malaria in adults, two tablets are usually taken once a week on exactly the same day of each week. The first dose is taken 1-2 weeks before traveling to an area where malaria is common, and then doses are continued for 8 weeks after exposure. For treatment of acute attacks of malaria in adults, four tablets are usually taken right away, followed by two tablets 6-8 hours later and then two tablets on each of the next 2 days.

For prevention or treatment of malaria in infants and children, the amount of hydroxychloroquine is based on the child's weight. Your doctor will calculate this amount and tell you how much hydroxychloroquine your child should receive.

For lupus erythematosus, one or two tablets are usually taken once or twice daily. For rheumatoid arthritis, one to three tablets are usually taken once a day.

Hydroxychloroquine can be taken with a glass of milk or a meal to decrease stomach upset. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take hydroxychloroquine exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

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SIDE EFFECTS

Hydroxychloroquine may cause side effects.Tell your doctor if any of these symptoms are severe or do not go away:

* headache
* dizziness
* loss of appetite
* upset stomach
* diarrhea
* stomach pain
* vomiting
* skin rash

If you experience any of the following symptoms, call your doctor immediately:

* reading or seeing difficulties (words, letters, or parts of objects missing)
* sensitivity to light
* blurred distance vision
* seeing light flashes or streaks
* difficulty hearing
* ringing in ears
* muscle weakness
* bleeding or bruising of the skin
* bleaching or loss of hair
* mood or mental changes
* irregular heartbeat
* drowsiness
* convulsions

PRECAUTIONS

Tell your doctor if you have: liver disease, blood disorders, psoriasis, allergies (especially drug allergies). This drug should be used only if clearly needed during pregnancy. Since small amounts of this medication are found in breast milk; consult your doctor before breast-feeding.

Antimalarial compounds should be used with caution in patients with hepatic disease or alcoholism or in conjunction with known hepatotoxic drugs.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.

INTERACTION

A type of enzyme deficiency (enzyme G6PD) found most frequently in those of African descent can develop into severe anemia and should also be monitored
Children are more sensitive to hydroxychloroquine than adults are, and small doses can be potentially fatal.

Hydroxychloroquine generally does not have significant interactions with other medications but care should be taken if combined with medication altering liver function as well as Aurothioglucose (Solganal), Cimetidine (Tagamet) or Digoxin (Lanoxin). It will transfer into breastmilk and should be used with care by pregnant or nursing mothers.

Tell your doctor of any over-the-counter or prescription medication you may take. Do not start or stop any medicine without doctor or pharmacist approval.

DRUG DESCRIPTION

Hydroxychloroquine is classified as an anti-malarial medication, and is one of a number of drugs which have been used for many years in the treatment of malaria. It is useful in treating systemic lupus erythematosus as well as rheumatoid arthritis and Sjögren's Syndrome (all rheumatic disorders). While hydroxychloroquine has been known for some time to decrease lysosomal pH in antigen presenting cells, its mechanism of action in inflammatory conditions has been recently elucidated and involves blocking the activation of toll-like receptors on plasmacytoid dendritic cells (PDCs). Toll-like receptor 9 (TLR 9), which recognizes DNA-containing immune complexes leads to the production of interferon and causes the dendritic cells to mature and present antigen to T cells. Hydroxychloroquine, by decreasing TLR signaling reduces the activation of dendritic cells, thus mitigating the inflammatory process.

Hydroxychloroquine is also widely used in the treatment of chronic Lyme disease, in combination with macrolide antibiotics such as clarithromycin. It is thought that the hydroxychloroquine raises the pH in cellular vacuoles in which semi-dormant Lyme spirochaetes live, allowing the effect the macrolide to suppress protein synthesis by the spirochaetes.

Hydroxychloroquine sulfate is a colorless crystalline solid, soluble in water to at least 20 percent; chemically the drug is 2-[[4-[(7-Chloro-4-quinolyl) amino]pentyl] ethylamino] ethanol sulfate (1:1).

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:
http://www.tajapi.com
or by contacting the sponsor, Taj Pharmaceuticals Limited., at:
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