HYDROXYCHLOROQUINE SULFATE- hydroxychloroquine sulfate tablet, film coated
DIRECT RX

HYDROXYCHLOROQUINE SULFATE

BOXED WARNING SECTION

WARNING

PHYSICIANS SHOULD COMPLETELY FAMILIARIZE THEMSELVES WITH THE COMPLETE CONTENTS OF THIS LEAFLET BEFORE PRESCRIBING HYDROXYCHLOROQUINE.

DESCRIPTION SECTION

Hydroxychloroquine sulfate is an odorless, white or practically white crystalline powder, freely soluble in water; practically insoluble in alcohol, in chloroform, and in ether. Chemically the drug is 2-[[4-[(7-Chloro-4-quinolyl) amino] pentyl] ethylamino] ethanol sulfate (1:1).

Each hydroxychloroquine sulfate tablet intended for oral administration contains 200 mg of hydroxychloroquine sulfate equivalent to 155 mg base. In addition, each tablet contains the following inactive ingredients: dibasic calcium phosphate dihydrate, magnesium stearate, pregelatinized starch, polyethylene glycol, polyvinyl alcohol, starch, talc and titanium dioxide.

CLINICAL PHARMACOLOGY SECTION

The drug possesses antimalarial actions and also exerts a beneficial effect in lupus erythematosus (chronic discoid or systemic) and acute or chronic rheumatoid arthritis. The precise mechanism of action is not known.

INDICATIONS & USAGE SECTION

Hydroxychloroquine sulfate tablets are indicated for the suppressive treatment and treatment of acute attacks of malaria due to Plasmodium vivax, P. malariae, P. ovale, and susceptible strains of P. falciparum. It is also indicated for the treatment of discoid and systemic lupus erythematosus, and rheumatoid arthritis.

CONTRAINDICATIONS SECTION

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

WARNINGS SECTION

General

Hydroxychloroquine sulfate tablets are not effective against chloroquine-resistant strains of P. falciparum.

Children are especially sensitive to the 4-aminoquinoline compounds. A number of fatalities have been reported following the accidental ingestion of chloroquine, sometimes in relatively small doses (0.75 g or 1 g in one 3-year-old child). Patients should be strongly warned to keep these drugs out of the reach

of children.

Use of hydroxychloroquine sulfate tablets in patients with psoriasis may precipitate a severe attack of psoriasis. When used in patients with porphyria the condition may be exacerbated. The preparation should not be used in these conditions unless in the judgment of the physician the benefit to the patient outweighs the possible hazard.

Usage in Pregnancy

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.

PRECAUTIONS SECTION

General

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.

OVERDOSAGE SECTION

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. 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. 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. If finely powdered, activated charcoal is introduced by the stomach tube, after lavage, and within 30 minutes after ingestion of the tablets, it may inhibit further intestinal absorption of the drug. To be effective, the dose of activated charcoal should be at least five times the estimated dose of hydroxychloroquine ingested. Convulsions, if present, should be controlled before attempting gastric lavage. If 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. Because of the importance of supporting respiration, tracheal intubation or tracheostomy, followed by gastric lavage, may also be necessary. Exchange transfusions have been used to reduce the level of 4-aminoquinoline drug in the blood.

A patient who survives the acute phase and is asymptomatic should be closely observed for at least six hours. Fluids may be forced, and sufficient ammonium chloride (8 g daily in divided doses for adults) may be administered for a few days to acidify the urine to help promote urinary excretion in cases of both overdosage and sensitivity.

HOW SUPPLIED SECTION

Hydroxychloroquine Sulfate Tablets, USP contain 200 mg of hydroxychloroquine sulfate, equivalent to

155 mg base, are white to off-white, capsule-shaped, biconvex, film-coated tablets debossed with "ZC38" on one side and plain on other side, and are supplied as follows:

NDC 68382-096-01 in bottles of 100 tablets

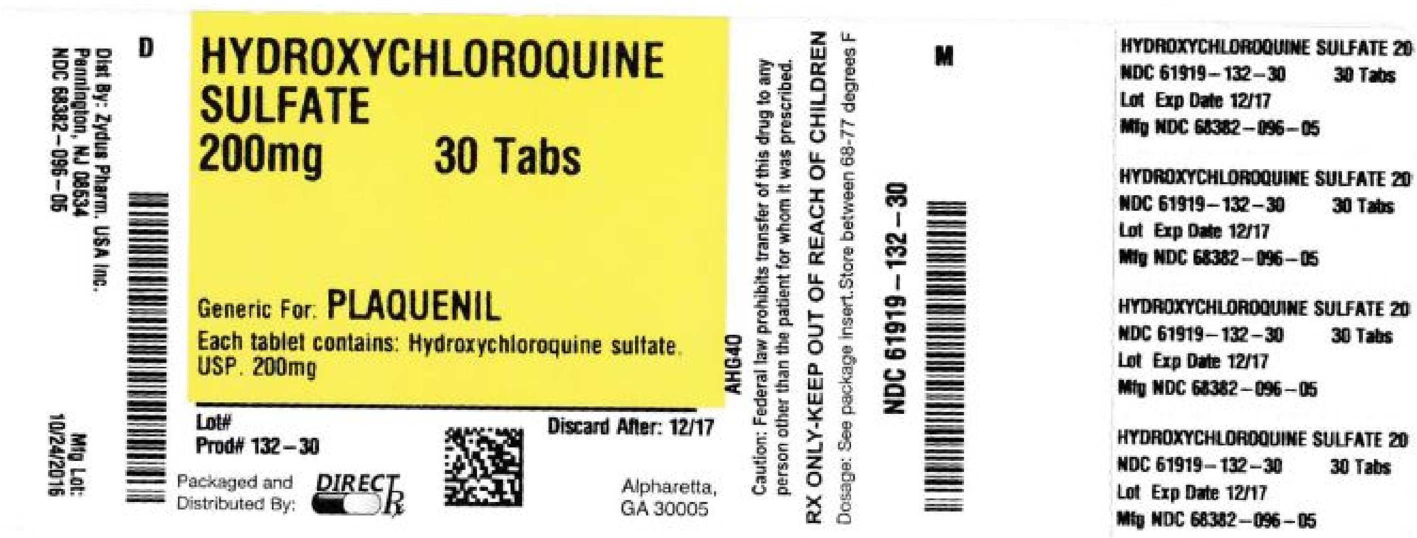
NDC 68382-096-05 in bottles of 500 tablets

NDC 68382-096-30 in unit-dose blister cartons of 100 (10 x 10) unit dose tablets

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Dispense in a tight, light-resistant container as defined in the USP/NF.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



HYDROXYCHLOROQUINE SULFATE			
hydroxychloroquine sulfate tablet, film coated			

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:61919-132(NDC:68382-096)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROXYCHLOROQUINE SULFATE (UNII: 8Q2869CNVH) (HYDROXYCHLOROQUINE - UNII:4QWG6N8QKH)	HYDROXYCHLOROQUINE SULFATE	200 mg

Inactive Ingredients	
Ingredient Name	**Strength**
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	white	**Score**	score with uneven pieces
Shape	OVAL	**Size**	13mm
Flavor		**Imprint Code**	ZC38
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61919-132-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040657	01/01/2014	

Labeler - DIRECT RX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	relabel(61919-132) , repack(61919-132)

Revised: 10/2016 DIRECT RX