PRIMAQUINE PHOSPHATE- primaquine phosphate tablet
Aidarex Pharmaceuticals LLC

PRIMAQUINE
PHOSPHATE
TABLETS, USP

WARNING

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

DESCRIPTION

Primaquine phosphate is 8-[(4-Amino-1-methylbutyl)amino]-6-methoxyquinoline phosphate, a synthetic compound with potent antimalarial activity. Each tablet contains 26.3 mg of Primaquine phosphate (equivalent to 15 mg of primaquine base). The dosage is customarily expressed in terms of the base.

Inactive Ingredients: Microcrystalline Cellulose, Pregelatinized Starch, Lactose Monohydrate, Magnesium Stearate, Purified water, Hypromellose, Opadry Purple, Titanium Dioxide, Macrgol/PEG, FD&C Red #40 and FD&C Blue #2.

CLINICAL PHARMACOLOGY

Primaquine phosphate is an 8-aminoquinoline compound which eliminates tissue (exoerythrocytic) infection. Thereby, it prevents the development of the blood (erythrocytic) forms of the parasite which are responsible for relapses in vivax malaria. Primaquine phosphate is also active against gametocytes of *Plasmodium falciparum*.

INDICATIONS AND USAGE

Primaquine phosphate is indicated for the radical cure (prevention of relapse) of vivax malaria.

CONTRAINDICATIONS

Primaquine phosphate is contraindicated in acutely ill patients suffering from systemic disease manifested by tendency to granulocytopenia, such as rheumatoid arthritis and lupus erythematosus. The drug is also contraindicated in patients receiving concurrently other potentially hemolytic drugs or depressants of myeloid elements of the bone marrow.

Because quinacrine hydrochloride appears to potentiate the toxicity of antimalarial compounds which are structurally related to primaquine, the use of quinacrine in patients receiving primaquine is contraindicated. Similarly, Primaquine should not be administered to patients who have received quinacrine recently, as toxicity is increased.

WARNINGS

Discontinue the use of Primaquine phosphate promptly if signs suggestive of hemolytic anemia occur (darkening of the urine, marked fall of hemoglobin or erythrocytic count).

Hemolytic reactions (moderate to severe) may occur in individuals with glucose-6-phosphate dehydrogenase (G-6-PD) deficiency and in individuals with a family or personal history of favism.

Areas of high prevalence of G-6-PD deficiency are Africa, Southern Europe, Mediterranean region, Middle East, South-East Asia, and Oceania. People from these regions have a greater tendency to develop hemolytic anemia (due to a congenital deficiency of erythrocytic glucose-6-phosphate dehydrogenase) while receiving Primaquine and related drugs.

Usage in Pregnancy

Safe usage of this preparation in pregnancy has not been established. Therefore, use of it during pregnancy should be avoided except when in the judgment of the physician the benefit outweighs the possible hazard.

PRECAUTIONS

Since anemia, methemoglobinemia, and leukopenia have been observed following administration of large doses of primaquine, the adult dosage of 1 tablet (= 15 mg base) daily for fourteen days should not be exceeded. It is also advisable to make routine blood examinations (particularly blood cell counts and hemoglobin determinations) during therapy.

If primaquine phosphate is prescribed for (1) an individual who has shown a previous idiosyncrasy to primaquine phosphate (as manifested by hemolytic anemia, methemoglobinemia, or leukopenia), (2) an individual with a family or personal history of favism, or (3) an individual with erythrocytic glucose-6-phosphate dehydrogenase (G-6-PD) deficiency or nicotinamide adenine dinucleotide (NADH) methemoglobin reductase deficiency, the person should be observed closely for tolerance. The drug should be discontinued immediately if marked darkening of the urine or sudden decrease in hemoglobin concentration or leukocyte count occurs.

Due to potential for QT interval prolongation, monitor ECG when using Primaquine in patients with cardiac disease, long QT syndrome, a history of ventricular arrhythmias, uncorrected hypokalemia and/or hypomagnesemia, or bradycardia (<50 bpm), and during concomitant administration with QT interval prolonging agents (see PRECAUTIONS, Drug Interactions, ADVERSE REACTIONS, and OVERDOSAGE).

Drug Interactions

Caution is advised if Primaquine is used concomitantly with other drugs that prolong the QT interval (see PRECAUTIONS, ADVERSE REACTIONS, and OVERDOSAGE).

Geriatric Use

Clinical studies of Primaquine did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

ADVERSE REACTIONS

Gastrointestinal: nausea, vomiting, epigastric distress, and abdominal cramps.

Hematologic: leukopenia, hemolytic anemia in glucose-6-phosphate dehydrogenase (G-6-PD) deficient individuals, and methemoglobinemia in nicotinamide adenine dinucleotide (NADH) methemoglobin reductase deficient individuals.

Cardiac: Cardiac Arrhythmia and QT interval prolongation (see PRECAUTIONS, OVERDOSAGE).

OVERDOSAGE

Symptoms of overdosage of primaquine phosphate include abdominal cramps, vomiting, burning epigastric distress, central nervous system and cardiovascular disturbances, including cardiac arrhythmia and QT interval prolongation, cyanosis, methemoglobinemia, moderate leukocytosis or leukopenia, and anemia. The most striking symptoms are granulocytopenia and acute hemolytic anemia in sensitive persons. Acute hemolysis occurs, but patients recover completely if the dosage is discontinued.

DOSAGE AND ADMINISTRATION

Primaquine phosphate is recommended only for the radical cure of vivax malaria, the prevention of relapse in vivax malaria, or following the termination of chloroquine phosphate suppressive therapy in an area where vivax malaria is endemic. Patients suffering from an attack of vivax malaria or having parasitized red blood cells should receive a course of chloroquine phosphate, which quickly destroys the erythrocytic parasites and terminates the paroxysm. Primaquine phosphate should be administered concurrently in order to eradicate the exoerythrocytic parasites in a dosage of 1 tablet (equivalent to 15 mg base) daily for 14 days.

HOW SUPPLIED

Primaquine Phosphate USP Tablets are solid oral formulation round tablet debossed "BY4" available in 26.3 mg and 14, 28, and 100 count.

Available in bottles of 100. (NDC 33261-0671-14)

Available in bottles of 100. (NDC 33261-0671-28)

Available in bottles of 100. (NDC 33261-0671-00)

Store at controlled room temperature: 25°C (77°F); excursions are permitted to 15°-30°C (59°-86°F) [see USP Controlled Room Temperature].

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

Clinical Studies

Persons with acute attacks of vivax malaria, provoked by the release of erythrocytic forms of the parasite, respond readily to therapy, particularly to Chloroquine Phosphate. Primaquine eliminates tissue (exoerythrocytic) infection and prevents relapses in experimentally induced vivax malaria in human volunteers and in persons with naturally occurring infections and is a valuable adjunct to conventional therapy in vivax malaria.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA1088.

Rx Only

Manufactured for:

Bayshore Pharmaceuticals LLC
Short Hills, NJ 07078
1-800-593-5725

Repackaged By:

Aidarex Pharmaceuticals, LLC

Corona, CA 92882

Revised 10/2015

PRINCIPAL DISPLAY PANEL - 26.3 mg Tablet Bottle Label

NDC 76385-102-01
Primaquine phosphate Tablets, USP
26.3 mg (=15 mg base)

Rx only

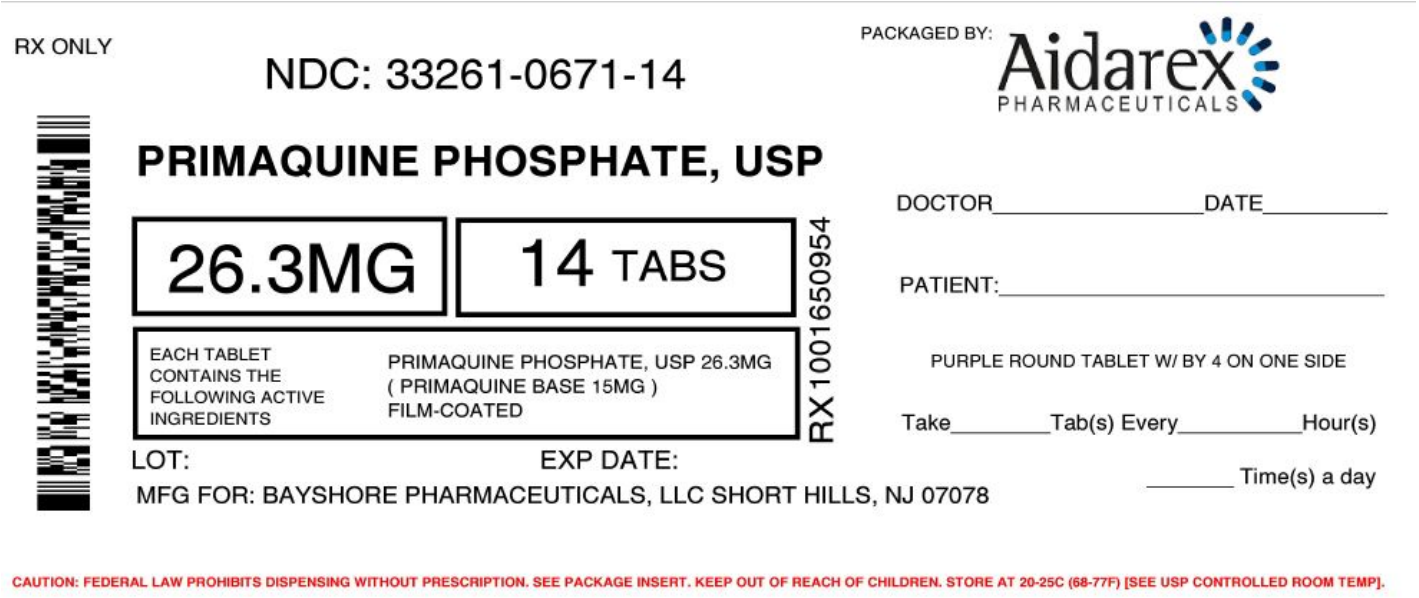
100 Tablets

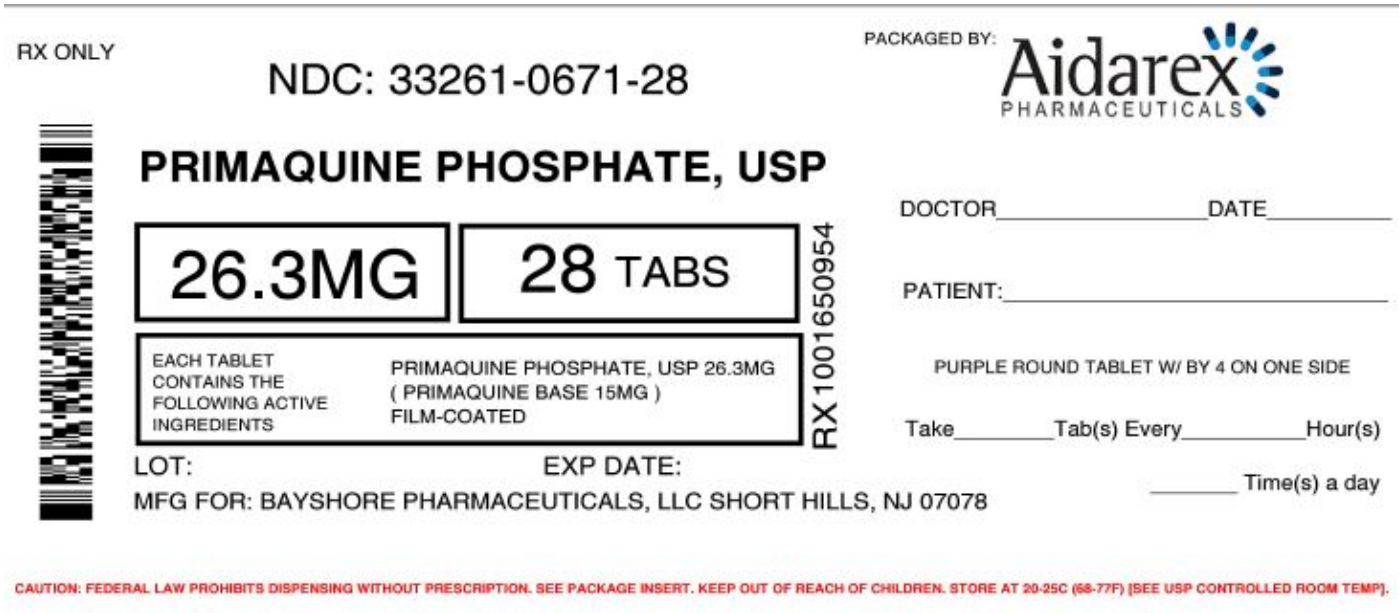
Adult dosage should not exceed 1 tablet daily for 14 days.

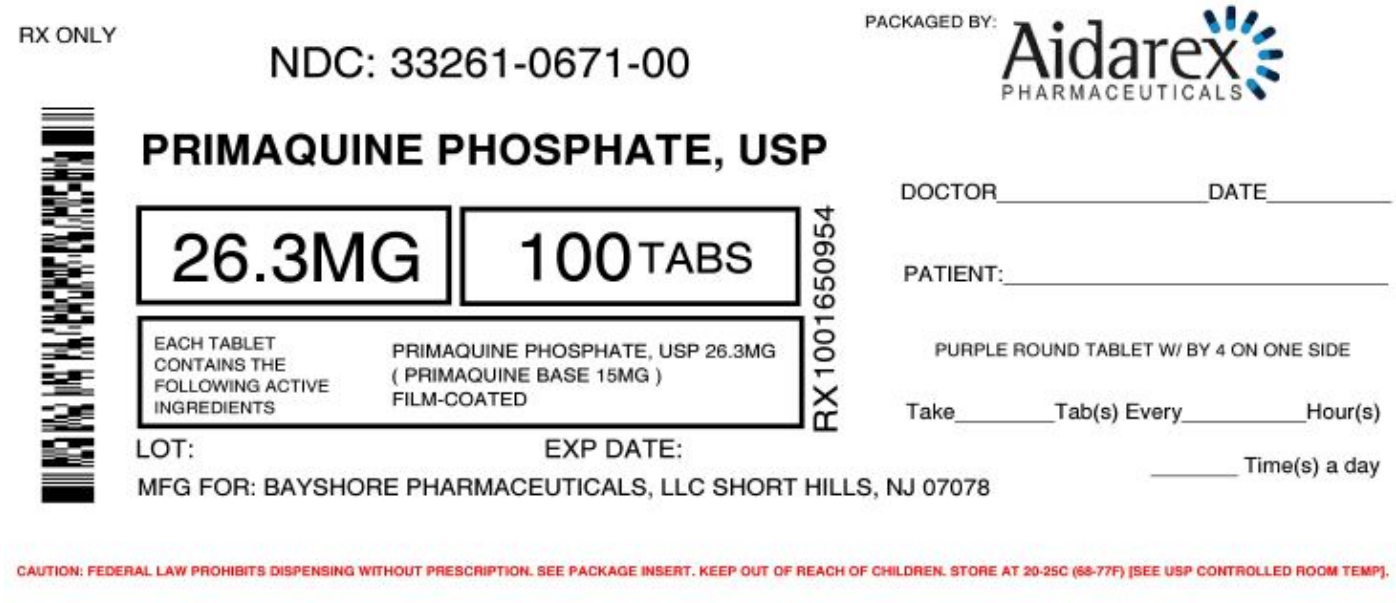
Discontinue promptly if signs suggestive of hemolytic anemia occur (i.e., darkening of urine, marked fall of hemoglobin, or erythrocyte count). Usual Dosage: See package insert.

Dispense in tight, light-resistant container as defined in the USP/NF. Store at 25° C (77° F); excursions permitted to 15° C-30° C (59° F-86° F) [see USP Controlled Room Temperature].

Manufactured for: Bayshore Pharmaceuticals LLC
Short Hills, NJ 07078







PRIMAQUINE PHOSPHATE

primaquine phosphate tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:33261-671(NDC:76385-102)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PRIMAQUINE PHOSPHATE (UNII: H0982HF78B) (PRIMAQUINE - UNII:MVR3634GX1)	PRIMAQUINE	15 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
WATER (UNII: 059QF0KO0R)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	

Product Characteristics			
Color	PURPLE	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	BY4
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:33261-671-00	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2014	
2	NDC:33261-671-14	14 in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2014	
3	NDC:33261-671-28	28 in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204476	08/01/2014	

Labeler - Aidarex Pharmaceuticals LLC (801503249)

Revised: 7/2017 Aidarex Pharmaceuticals LLC