Only for the use of medical professionals

Remaquin®

Primaquine phosphate tablets USP

Description

Remaquin® is a preparation of primaquine phosphate. It is an 8-[(4-Amino-1-methylbutyl) amino]-6-methoxyquinoline Antiprotozoal agent which is highly active against exo-erythrocytic stages of *Plasmodium vivax*, *Plasmodium ovale* and against the primary exo-erythrocytic stages of *Plasmodium falciparum*. Primaquine is also highly active against gametocytes of Plasmodia, especially *Plasmodium falciparum*.

Indications

Remaquin® is indicated:

- For the radical cure of vivax and ovale malaria
- Prevention of relapse in vivax and ovale malaria or following the termination of chloroquine phosphate suppressive therapy in an area where vivax or ovale malaria are endemic.

Remaquin® is generally initiated during the last 2 weeks of, or immediately following, therapy with chloroquine or another suitable antimalarial agent.

Dosage and Administration

Adults: 1 tablet (15 mg primaquine base) daily for 14 days.
Children: 0.39mg/ kg body weight primaquine base daily for 14 days
NOTE: For radical cure of some strains of Plasmodium vivax, higher doses or longer courses may be required to overcome resistance.

Pregnancy and lactation

The safety of primaquine in human pregnancy has not been established. It should therefore be avoided during pregnancy unless in the judgment of the physician the benefits outweigh the possible hazard. It is not known whether primaquine is excreted in breast milk. Because of the potential of primaquine to produce serious adverse reactions in nursing infants, a decision should be made whether to discontinue breast-feeding or to discontinue the drug.

Side effects

The most common side effects of primaquine are Gastrointestinal**;** nausea, vomiting, epigastric distress, and abdominal pain if administered in empty stomach. Other side effect includes hematologic**;** leukopenia, hemolytic anemia especially in G-6-PD deficient individuals and methemoglobinemia especially in NADH methemoglobin reductase deficient individuals.

Overdose

Symptoms of overdosage of primaquine phosphate are abdominal cramps, vomiting, burning epigastric distress, central nervous system and cardiovascular disturbances, 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.

Contraindications

Primaquine is contraindicated in patients who are hypersensitive to primaquine and to any of its ingredients. It 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.

Precautions
Anemia, methemoglobinemia and leukopenia have been observed following administration of large doses of primaquine; therefore, the adult dosage of 1 tablet daily for 14 days should not be exceeded. It is also advisable to make routine blood examinations, particularly blood cell counts and hemoglobin determinations, during therapy. Discontinue the use of primaquine promptly if signs suggestive of hemolytic anemia occur (such as darkening of the urine or a sudden decrease in hemoglobin concentration or erythrocyte count), or if there is a sudden decrease in leukocyte count. Observe particular caution in individuals with a personal or family history of favism, hemolytic anemia, or glucose-6-phosphate dehydrogenase (G-6-PD) deficiency or nicotinamide adenine dinucleotide (NADH) methemoglobin reductase deficiency.

Drug interactions
Primaquine inhibits hepatic drug oxidation and is reported to inhibit the metabolism of chloroquine.

Pharmaceutical precautions
Keep in a cool, dry, dark place.

Presentation
Remaquin® Tablet: Each tablet contains primaquine 15mg as phosphate USP.

Packaging Quantities
Remaquin® Tablet: Carton of 100 tablets in Alu-PVC blister.

® Registered Trade Mark

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