

Aralen[®] (chloroquine) – New warnings

- On July 13, 2017, the [FDA approved](#) updates to the *Warnings* section of the [Aralen \(chloroquine\)](#) drug label regarding treatment of exoerythrocytic forms of malaria, cardiac effects, and hypoglycemia.
- Aralen is indicated for the treatment of uncomplicated malaria due to susceptible strains of *P. falciparum*, *P. malariae*, *P. ovale*, and *P. vivax*; prophylaxis of malaria in geographic areas where resistance to Aralen is not present; and for the treatment of extraintestinal amebiasis.
- Aralen does not treat the hypnozoite liver stage forms of *Plasmodium* and will therefore not prevent relapses of malaria due to *P. vivax* or *P. ovale*. Additional treatment with an anti-malarial agent active against these forms, such as an 8-aminoquinoline, is required for the treatment of infections with *P. vivax* and *P. ovale*.
- Cases of cardiomyopathy resulting in cardiac failure, in some cases with fatal outcome, have been reported in patients treated during long term therapy at high doses with Aralen. Chronic toxicity should be considered when conduction disorders are diagnosed.
 - Patients should be monitored for signs and symptoms of cardiomyopathy and Aralen should be discontinued if cardiomyopathy develops.
 - If cardiotoxicity is suspected, prompt discontinuation of Aralen may prevent life-threatening complications.
- QT interval prolongation, torsades de pointes, and ventricular arrhythmias have also been reported with Aralen use. Some cases have been fatal.
 - The risk for conduction disorders is greater if Aralen is administered at high doses.
 - Aralen should be used with caution in patients with cardiac disease, a history of ventricular arrhythmias, uncorrected hypokalemia and/or hypomagnesemia, or bradycardia (< 50 beats per minute), and during concomitant administration with QT interval prolonging agents due to potential for QT interval prolongation.
- Aralen has been shown to cause severe hypoglycemia including loss of consciousness that could be life-threatening in patients treated with or without antidiabetic medications.
 - Patients treated with Aralen should be warned about the risk of hypoglycemia and the associated clinical signs and symptoms.
 - Patients presenting with clinical symptoms suggestive of hypoglycemia during treatment with Aralen should have their blood glucose level checked and treatment reviewed as necessary.