

## Plaquenil® (hydroxychloroquine) – New Warnings

- On January 27, 2017, the [FDA approved](#) new updates to the *Warnings* section of the [Plaquenil \(hydroxychloroquine\)](#) drug label regarding cardiac effects, including cardiomyopathy and QT prolongation, and hypoglycemia.
- Plaquenil is indicated for the treatment of uncomplicated malaria due to *Plasmodium falciparum*, *Plasmodium malariae*, *Plasmodium ovale*, and *Plasmodium vivax*, and for the prophylaxis of malaria in geographic areas where [chloroquine](#) resistance is not reported.
  - Refer to the Plaquenil drug label for specific limitations of use for the treatment of malaria.
- Plaquenil is also indicated for the treatment of chronic discoid lupus erythematosus and systemic lupus erythematosus in adults, and for the treatment of acute and chronic rheumatoid arthritis in adults.
- Postmarketing cases of life-threatening and fatal cardiomyopathy have been reported with use of Plaquenil and chloroquine. Patients may present with atrioventricular (AV) block, pulmonary hypertension, sick sinus syndrome or with cardiac complications. ECG findings may include AV, right or left bundle branch block.
  - Signs or symptoms of cardiac compromise have appeared during acute and chronic treatment. Clinical monitoring for signs and symptoms of cardiomyopathy is advised, including use of appropriate diagnostic tools (eg, ECG) to monitor patients for cardiomyopathy during Plaquenil therapy.
  - Chronic toxicity should be considered when conduction disorders (bundle branch block/AV heart block) or biventricular hypertrophy are diagnosed. If cardiotoxicity is suspected, prompt discontinuation of Plaquenil may prevent life-threatening complications.
  - Plaquenil prolongs the QT interval. Ventricular arrhythmias and torsades de pointes have been reported in patients taking Plaquenil. Plaquenil should not be administered with other drugs that have the potential to prolong the QT interval.
- Plaquenil 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 Plaquenil should be warned about the risk of hypoglycemia and the associated clinical signs and symptoms. Patients presenting with hypoglycemia symptoms during Plaquenil treatment should be evaluated.
- In addition, the Plaquenil label no longer lists the following as contraindications: presence of retinal or visual field changes attributable to any 4-aminoquinoline compound, or for long-term therapy in children.
- A new *Drug Interactions* section was added to the Plaquenil drug label with information regarding use with [digoxin](#), insulin or diabetic drugs, drugs that prolong QT interval and other arrhythmogenic drugs, [mefloquine](#) and other drugs known to lower the convulsive threshold, antiepileptics, [methotrexate](#), [cyclosporine](#), [Biltricide® \(praziquantel\)](#), antacids and kaolin, [cimetidine](#), and [ampicillin](#).