RXADVANCE
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CLINICAL UPDATE

Brand Name	Plaquenil
Generic Name	hydroxychloroquine; chloroquine

Clinical Update

FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems.

FDA Approval Date: April 24, 2020

Safety

Hydroxychloroquine and chloroquine are FDA-approved to treat or prevent malaria. Hydroxychloroquine is also FDA-approved to treat autoimmune conditions such as chronic discoid lupus erythematosus, systemic lupus erythematosus in adults, and rheumatoid arthritis.

The FDA is aware of reports of serious heart rhythm problems in patients with COVID-19 treated with hydroxychloroquine or chloroquine, often in combination with azithromycin and other QT prolonging medicines. We are also aware of increased use of these medicines through outpatient prescriptions**.** FDA will continue to investigate risks associated with the use of hydroxychloroquine and chloroquine for COVID-19. Hydroxychloroquine and chloroquine can cause abnormal heart rhythms such as QT interval prolongation and a dangerously rapid heart rate called ventricular tachycardia. These risks may increase when these medicines are combined with other medicines known to prolong the QT interval, including the antibiotic azithromycin, which is also being used in some COVID-19 patients without FDA approval for this condition. Patients who also have other health issues such as heart and kidney disease are likely to be at increased risk of these heart problems when receiving these medicines. Hydroxychloroquine and chloroquine have not been shown to be safe and effective for treating or preventing COVID-19. They are being studied in clinical trials for COVID-19, and therefore their temporary use during the COVID-19 pandemic for treatment of the virus in hospitalized patients when clinical trials are not available, or participation is not feasible, through an Emergency Use Authorization (EUA). The medicines being used under the hydroxychloroquine/chloroquine EUA are supplied from the Strategic National Stockpile, the national repository of critical medical supplies to be used during public health emergencies. This safety communication reminds physicians and the public of risk information set out in the hydroxychloroquine and chloroquine healthcare provider fact sheets that were required by the EUA.

To decrease the risk of these heart problems that can be life-threatening, public is being warned that hydroxychloroquine and chloroquine, either alone or combined with azithromycin, when used for COVID-19 should be limited to clinical trial settings or for treating certain hospitalized patients under the EUA. FDA will continue to investigate risks associated with the use of hydroxychloroquine and chloroquine for COVID-19. The EUA was based upon limited evidence that the medicines may provide benefit, and for this reason, therefore their use is authorized only in hospitalized patients under careful heart monitoring. Patients taking hydroxychloroquine or chloroquine for FDA-approved indications to treat malaria or autoimmune conditions should continue taking their medicine as prescribed. The benefits of these medicines outweigh the risks at the recommended doses for these conditions. Do not stop taking medicine without first talking to your health care professional. Be aware that there are no proven treatments for COVID-19 and no vaccine. If you are receiving hydroxychloroquine or chloroquine for COVID-19 and experience irregular heartbeats, dizziness, or fainting, seek medical attention right away.

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Initial evaluation and monitoring is recommended when using hydroxychloroquine or chloroquine under the EUA or in clinical trials that investigate these medicines for the treatment or prevention of COVID-19. Monitoring may include baseline ECG, electrolytes, renal function, and hepatic tests. Be aware that hydroxychloroquine or chloroquine can:

- cause QT prolongation
- increase the risk of QT prolongation in patients with renal insufficiency or failure
- increase insulin levels and insulin action causing increased risk of severe hypoglycemia
- cause hemolysis in patients with Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency
- interact with other medicines that cause QT prolongation even after discontinuing the medicines due to their long half-lives of approximately 30-60 days.

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