

## FDA Drug Safety Communication

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

*Does not affect FDA-approved uses for malaria, lupus, and rheumatoid arthritis*

### Safety Announcement [04-24-2020]

#### What safety concern is FDA announcing?

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. Therefore, we would like to remind health care professionals and patients of the known risks associated with both hydroxychloroquine and chloroquine. FDA will continue to investigate risks associated with the use of hydroxychloroquine and chloroquine for COVID-19 and communicate publicly when we have more information.

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 we authorized 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.

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.

#### What is FDA doing?

To decrease the risk of these heart problems that can be life-threatening, we are warning the public 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, and we will communicate publicly when we have more information.

#### What are hydroxychloroquine and chloroquine and how can they help me?

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 EUA was based upon [limited evidence](#) that the medicines may provide benefit, and for this reason, we authorized their use only in hospitalized patients under careful heart monitoring.

### **What should patients and parents/caregivers do?**

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 your medicine without first talking to your health care professional, and talk to them if you have any questions or concerns.

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 by calling 911.

Do not buy these medicines from online pharmacies without a prescription from your health care professional. Consumers should not take any form of chloroquine that has not been prescribed for them by a healthcare professional. Serious poisoning and death have been reported after mistaken use of a [chloroquine product not intended to be taken by humans](#). If you have these medicines in your home, keep them in childproof containers out of the reach of children to prevent [accidental poisoning](#).

### **What should health care professionals do?**

We recommend initial evaluation and monitoring 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

If a healthcare professional is considering use of hydroxychloroquine or chloroquine to treat or prevent COVID-19, FDA recommends checking [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for a suitable clinical trial and consider enrolling the patient. Consider using [resources](#) available to assess a patient's risk of QT prolongation and mortality.

### **What did FDA find?**

We have reviewed case reports in the [FDA Adverse Event Reporting System database](#), the published medical literature, and the American Association of Poison Control Centers National Poison Data System concerning serious heart-related adverse events and death in patients with COVID-19 receiving hydroxychloroquine and chloroquine, either alone or combined with azithromycin or other QT prolonging medicines. These adverse events were reported from the hospital and outpatient settings for treating or preventing COVID-19, and included QT interval prolongation, ventricular tachycardia and ventricular fibrillation, and in some cases death. We are continuing to investigate these safety risks in patients with COVID-19 and will communicate publicly when more information is available.

### **How do I report side effects from hydroxychloroquine and chloroquine?**

To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving hydroxychloroquine and chloroquine or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

## Related Information

- [COVID-19 FAQs](#)
- [FAQs on Emergency Use Authorization for Chloroquine and Hydroxychloroquine](#)
- [Poison Control](#)
- [CredibleMeds: QT Drugs Database](#)
- [NIH COVID-19 Treatment Guidelines](#)
- [The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective](#)
- [Think It Through: Managing the Benefits and Risks of Medicines](#)