

June 2020

FDA revokes the use of Hydroxychloroquine Emergency Use Authorization (EUA) for the treatment of COVID-19

Hydroxychloroquine (HCQ) is a medication that has been used for many years in the treatment of malaria, rheumatoid arthritis, systemic lupus erythematosus and porphyria cutanea tarda. On March 28, 2020, the FDA issued an Emergency Use Authorization of oral formulations of hydroxychloroquine to be distributed from the Strategic National Stockpile as a *potential* treatment for COVID-19 in certain hospitalized patients.

The FDA has concluded that hydroxychloroquine has not demonstrated effectiveness in treating or preventing COVID-19 and has revoked the EUA for hydroxychloroquine and chloroquine (HCQ) based upon the following reasons:

- The suggested dosing regimens for chloroquine (CQ) and HCQ as detailed in the Fact Sheets are unlikely to produce an antiviral effect.
- Earlier reports of decreased viral shedding with CQ or HCQ treatment have not been consistently replicated and recent data from a randomized controlled trial assessing probability of negative conversion showed no difference between HCQ and standard of care alone.
- Current U.S. treatment guidelines do not recommend the use of CQ or HCQ in hospitalized patients with COVID-19 outside of a clinical trial, and the NIH guidelines now recommend against such use outside of a clinical trial.
- Recent data from a large randomized controlled trial showed no evidence of benefit for mortality or other outcomes such as hospital length of stay or need for mechanical ventilation of HCQ treatment in hospitalized patients with COVID-19.

Frequently Asked Questions:

Can patients started on HCQ finish their treatment or do they need to stop using it now?

If a patient was started on HCQ as part of the EUA, they may finish out their therapy if desired and if found necessary by the patient's attending physician.

Can doctors still prescribe HCQ to treat COVID-19?

Yes, doctors can still prescribe HCQ off-label for patients with COVID-19; however, the FDA has not observed benefits with therapy and there are risks of serious adverse drug events with use.

The [news release](#) can be found on the [FDA press announcement website](#)

The [letter to Dr. Gary Disbrow and clinical trial data](#) can be found on the [FDA website](#)