

FDA warns against chloroquine for COVID-19 outside hospitals

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What's the news: The U.S. Food and Drug Administration (FDA) has cautioned against the use of some medicines FDA-approved to treat or prevent malaria and being used for the treatment or prevention of COVID-19. The FDA has warned that hydroxychloroquine and chloroquine should only be used in hospitals or clinical trials because they have been linked to a risk of heart rhythm problems, especially when paired with the antibiotic azithromycin.

Why it's important: There have been reports of serious, potentially life-threatening, heart rhythm problems in patients with COVID-19 who are treated with hydroxychloroquine or chloroquine and used 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,” says the FDA drug safety communication.

There is no evidence to show that hydroxychloroquine and chloroquine—prescribed for years to treat lupus and arthritis—are safe and effective for treating or preventing COVID-19. These medicines are currently being studied in clinical trials for COVID-19 treatment and prophylaxis. However, in late March the FDA issued an emergency use authorization (EUA) to supply chloroquine and hydroxychloroquine from the Strategic National Stockpile to treat certain patients who are hospitalized with COVID-19 and for whom clinical trials are not available, or participation is not feasible. Learn more about lessons learned from COVID-19, including how treatment is unclear at this time.

Hydroxychloroquine and chloroquine can cause abnormal heart rhythms such as QT interval prolongation and ventricular tachycardia. Risks may increase when combined with other medicines known to prolong the QT interval, including the antibiotic azithromycin, which is also being used in some patients with COVID-19 without FDA approval for this use. When patients have other underlying health issues such as heart disease or kidney disease, they are placed at an increased risk when receiving these medicines.

When used for COVID-19, hydroxychloroquine and chloroquine should be limited to clinical trial settings to decrease the risk of associated heart problems and other adverse events.

Learn more: The FDA continues to investigate risks associated with the use of these medicine for patients with COVID-19 and will communicate publicly when more information is available. For physicians and other health professionals, the FDA recommends initial evaluation and monitoring when using hydroxychloroquine or chloroquine under the EUA or in clinical trials. To mitigate risks of the unapproved use of chloroquine and hydroxychloroquine, the EUA includes certain mandatory requirements, including adverse event reporting to FDA MedWatch.

If a physician is considering the use of these medicines for COVID-19, the FDA recommends checking [ClinicalTrials.gov](https://clinicaltrials.gov) for a suitable clinical trial option for the patient. Additionally, consider using resources available to assess a patient's risk of QT prolongation and mortality.

Visit the FDA's frequently asked questions on the EUA for hydroxychloroquine and chloroquine for certain hospitalized patients with COVID-19.

For more related to hydroxychloroquine, see the joint statement of the American Medical Association, American Pharmacists Association and American Society of Health-System Pharmacists on ordering, prescribing or dispensing COVID-19 medications.

Stay up to speed on the AMA's COVID-19 advocacy efforts and track the fast-moving pandemic with the AMA's COVID-19 resource center, which offers a library of the most up-to-date resources from JAMA Network™, the Centers for Disease Control and Prevention, and the World Health Organization.

The AMA also created a physician's guide to COVID-19, which features resources on what evidence-based therapeutic options are available for patients.

Learn about seven medications to watch in global race to discover COVID-19 treatment.