

Chloroquine Tablets Safety Alert

Date of Notice: 04/24/2020

Brief Description of Safety Alert

On April 24, 2020, the FDA issued a safety warning regarding reports of serious heart rhythm problems in COVID-19 patients treated with hydroxychloroquine or chloroquine, often in combination with azithromycin or other QT prolonging drugs. Hydroxychloroquine and chloroquine have not been shown to be safe and effective for treating or preventing COVID-19; these drugs are currently being studied for the treatment of COVID-19.

Hydroxychloroquine and chloroquine can cause abnormal heart rhythms such as QT interval prolongation and dangerously rapid heart rate called ventricular tachycardia. These risks may increase when used in combination with other drugs known to prolong the QT interval.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
chloroquine 200mg tablets	All NDCs	All lots	All dates
hydroxychloroquine 200mg tablets	All NDCs	All lots	All dates
Plaquenil 200mg tablets	59212-562-10	All lots	All dates

Prescriber Information

The FDA has received case reports of serious heart-related adverse events and death in patients with COVID-19 receiving hydroxychloroquine and chloroquine, either alone or in combination with azithromycin or other QT prolonging drugs. The FDA recommends initial evaluation and monitoring when using hydroxychloroquine or chloroquine 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 for a suitable clinical trial and consider enrolling the patient.

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report [Online](#)
- Regular Mail or Fax: [Download form](#) or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Member Information

Members taking hydroxychloroquine or chloroquine for FDA-approved indications to treat malaria or autoimmune conditions should continue taking their drug as prescribed. The benefits of these drugs outweigh the risks at the recommended doses for these conditions. Do not stop taking your drug without first talking to your doctor and talk to them if you have any questions or concerns.

Be aware that there are no proven treatments or vaccine for COVID-19. 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.

RxAdvance Response

RxAdvance encourages members to contact their prescriber or pharmacist if you have questions about the use of hydroxychloroquine and chloroquine. If you are experiencing irregular heartbeats, dizziness or fainting, seek medical attention right away.

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.