

What data are available regarding the use of hydroxychloroquine sulfate (Plaquenil®), in combination with azithromycin (Zithromax®/Z-Pak®), for the treatment of COVID-19?

Initial response: March 25, 2020

Update: March 30, 2020

Summary of Changes

Additional information has become available from the Food and Drug Administration (FDA).

FDA Updates

- **March 27, 2020:** FDA's Center for Veterinary Medicine issued a warning to consumers and healthcare professionals that chloroquine phosphate, used to treat disease in aquarium fish, should not be used to treat COVID-19 in humans.¹
 - These products have not been evaluated for safety, effectiveness, and other factors in fish, let alone in humans.
 - The FDA is investigating a case in which 1 person died and another case where a person became very ill, after they reportedly took chloroquine phosphate used to treat their fish, to prevent COVID-19.
 - Patients should not take any form of chloroquine, unless prescribed by a licensed healthcare provider, and obtained through a legitimate source.

- **March 28, 2020:** FDA issued an Emergency Use Authorization (EUA) to Biomedical Advanced Research and Development Authority (BARDA) to allow hydroxychloroquine and chloroquine products, donated to the Strategic National Stockpile (SNS), to be distributed and prescribed by doctors, to hospitalized adolescent and adult patients with COVID-19, as appropriate, when a clinical trial is not available or feasible.^{2,3}
 - An EUA may be issued if the FDA determines that the known and potential benefits of the product, when used as intended, outweigh the known and potential risks of the product, and there are no adequate, approved, available alternatives.²
 - Pursuant to Section 564 of the Federal Food, Drug and Cosmetic Act (the Act), chloroquine and hydroxychloroquine products distributed from the SNS to public health authorities, for response to the COVID-19 pandemic:³
 - Must be administered by a healthcare provider pursuant to a valid prescription from a licensed practitioner, and
 - May only be used to treat adult and adolescent patients who weigh 50 kg (≥110 lb) or more, are hospitalized with COVID-19, and for whom a clinical trial is not available, or participation is not feasible.
 - The EUA requires that fact sheets, regarding the use of chloroquine and hydroxychloroquine for the treatment of COVID-19, be made available to healthcare providers and patients.² The fact sheets must contain information discussing the known risks and drug interactions associated with both drugs.

References: 1) FDA. FDA letter to stakeholders: Do not use chloroquine phosphate intended for fish as treatment for COVID-19 in humans. https://www.fda.gov/animal-veterinary/product-safety-information/fda-letter-stakeholders-do-not-use-chloroquine-phosphate-intended-fish-treatment-covid-19-humans?utm_campaign=FDA%20MedWatch%20-%20Chloroquine%20Phosphate%20Intended%20for%20Fish&utm_medium=email&utm_source=Eloqua. 2) HHS. HHS accepts donations of medicine to Strategic National Stockpile as possible treatments for COVID-19 patients. March 29, 2020. <https://www.hhs.gov/about/news/2020/03/29/hhs-accepts-donations-of-medicine-to-strategic-national-stockpile-as-possible-treatments-for-covid-19-patients.html>. 3) FDA. Request for Emergency Use Authorization for use of chloroquine phosphate or hydroxychloroquine sulfate supplied from the strategic national stockpile for treatment of 2019 coronavirus disease. <https://www.fda.gov/media/136534/download>.