

Hydroxychloroquine (Lexi-Tox)

Special Alerts

▼ Hydroxychloroquine and Chloroquine Safety Alert April 2020

The FDA has issued a safety communication cautioning against the use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to the risk of arrhythmias. Hydroxychloroquine and chloroquine can cause abnormal heart rhythms, such as QT interval prolongation and ventricular tachycardia. These risks may increase when hydroxychloroquine and chloroquine are administered in combination with other medicines known to prolong the QT interval, including azithromycin, which is also being used in COVID-19 patients without FDA approval. Patients with comorbidities such as heart and kidney disease may also be at an increased risk.

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. The FDA has issued an emergency use authorization that allows their temporary use during the COVID-19 pandemic for treatment of the virus in certain hospitalized patients when clinical trials are not available or participation in clinical trials is not feasible.

Further information may be found at <https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or>.

▼ Hydroxychloroquine and Chloroquine Phosphate Products Alert March 2020

The FDA has issued an emergency use authorization (EUA) to allow hydroxychloroquine sulfate and chloroquine phosphate products donated to the Strategic National Stockpile (SNS) to be distributed and used for certain hospitalized patients with COVID-19. These drugs will be distributed from the SNS to states for prescribers to use for adolescent and adult patients hospitalized with COVID-19, as appropriate, when a clinical trial is not available or participation is not feasible. The EUA requires that fact sheets that provide important information about using chloroquine phosphate and hydroxychloroquine sulfate in treating COVID-19 be made available to health care providers and patients/caregivers, including the known risks and drug interactions. The SNS will work with the Federal Emergency Management Agency to ship donated doses to states.

Hydroxychloroquine sulfate fact sheets – [Health care provider](#); [Patient](#)

Chloroquine phosphate fact sheets – [Health care provider](#); [Patient](#)

Further information may be found at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidtherapeutics>.

▼ COVID-19 Important Updates March 2020

At this time, while there are a number of medicines being investigated for treatment and/or prevention of COVID-19, none have yet to demonstrate safety and efficacy in humans diagnosed with or exposed to COVID-19. While there may be anecdotal support of certain medicines from the Chinese and European experiences, we continue to monitor developments and synthesize content based on expert clinical

experience and published literature and guidelines from major health organizations. Our UpToDate and Lexicomp infectious disease teams are continuously reviewing and updating our content for clinicians during this crisis.

Further information may be found at:

FDA: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-continues-facilitate-development-treatments>

CDC: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/therapeutic-options.html>

NIH National Library of Medicine: Clinicaltrials.gov <https://clinicaltrials.gov/ct2/results?cond=Covid-19&term=&cntry=&state=&city=&dist=>

Diagnosis and Management

For complete information outlining diagnosis and management, refer to 4-Aminoquinolines.

Brand Names: US

Plaquenil

Brand Names: Canada

APO-Hydroxyquine; JAMP Hydroxychloroquine Sulf; MINT-Hydroxychloroquine; MYLAN-Hydroxychloroquine [DSC]; Plaquenil; PRO-Hydroxychloroquine-200 [DSC]

Pharmacologic Category

Aminoquinoline (Antimalarial); Antimalarial Agent

CAS Registration

- 118-42-3

Breastfeeding Considerations

Hydroxychloroquine and the desethylchloroquine metabolite are present in breast milk (Cissoko 2010; Costedoat-Chalumeau 2002; Nation 1984; Ostensen 1985; Peng 2019).

Breast milk concentrations of hydroxychloroquine were evaluated in 33 women. All women were treated with hydroxychloroquine for at least 1 year for various connective tissue diseases and were 1 to 16 weeks' postpartum. Maternal doses ranged from 200 mg every other day to 200 mg twice daily. Sampling occurred over a 12-hour dosing period. The average relative infant dose (RID) of hydroxychloroquine was calculated by the authors of the study to be 1.9% to 3.2% of the weight-adjusted maternal dose. The highest RID (9.8%) was observed in one woman taking hydroxychloroquine 200 mg twice daily (Peng 2019).

In general, breastfeeding is considered acceptable when the RID is <10% (Anderson 2016; Ito 2000).

Infants exposed to hydroxychloroquine via breast milk following chronic maternal administration, including one infant who was exposed for 30 months (Cimaz 2004), have been monitored for adverse

effects; no negative impact on vision, growth, development, or otherwise has been noted (Cimaz 2004; Motta 2002; Motta 2005; Peng 2019; Tincani 2001).

The manufacturer recommends that caution be exercised when administering hydroxychloroquine to breastfeeding women. However, hydroxychloroquine is considered to be compatible with breastfeeding or low risk in breastfeeding mothers with autoimmune and systemic inflammatory diseases (ACR [Sammaritano 2020]; Flint 2016; Götestam 2016; Kavanaugh 2015;). Clinicians should note that when hydroxychloroquine is administered to breastfeeding women for malaria, insufficient amounts are transferred via breast milk to provide chemoprophylaxis to the infant (CDC 2020).

Interim guidance is available from the CDC for lactating women who are diagnosed with COVID-19 (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/inpatient-obstetric-healthcare-guidance.html>)

Dosage Forms: US

Tablet, Oral:

Plaquenil: 200 mg

Generic: 200 mg

Dosage Forms: Canada

Tablet, Oral:

Plaquenil: 200 mg

Generic: 200 mg

Index Terms

Coronavirus; COVID-19; Hydroxychloroquine Sulfate

References

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Last Updated 5/1/20