

## Chloroquine (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: Canada

TEVA-Chloroquine

Pharmacologic Category

Aminoquinoline (Antimalarial); Antimalarial Agent

CAS Registration

- 54-05-07

Breastfeeding Considerations

Chloroquine and its desethylchloroquine (DECQ) metabolite are present in breast milk.

Per product labeling, 11 lactating women with malaria were given a single oral dose of chloroquine 600 mg. The maximum daily dose to the breastfeeding infant was calculated to be 0.7% of the maternal dose. Additional information has been published and results are variable, likely due to various maternal doses and dosing regimens, routes of administration, and assay methods (Akintonwa 1988; Boelaert 2001; Deturmeny 1984; Edstein 1986; Ette 1987; Law 2008; Ogunbona 1987). Using data from available studies, the relative infant dose (RID) of chloroquine and its metabolite was calculated to be 0.9% to 9.5% (chloroquine) and 0.19% to 2.5% (DECQ). These RID calculations used a modified formula, based on average milk concentrations (not  $C_{max}$ ) and total days of maternal therapy (not a single daily dose) to take into consideration the intermittent dosing and long half-life of chloroquine (Law 2008). In general, breastfeeding is considered acceptable when the RID of a medication is <10% (Anderson 2016; Ito 2000).

Due to the potential for serious adverse reactions in the breastfeeding infant, the manufacturer recommends a decision be made to discontinue breastfeeding or to discontinue the drug, considering the importance of treatment to the mother.

Available guidelines consider the amount of chloroquine exposure to the nursing infant to be acceptable when used in normal maternal doses for malaria prophylaxis or treatment (CDC 2020; WHO 2002). The amount of chloroquine obtained by a breastfeeding infant from breast milk would not provide adequate

protection if therapy for malaria in the infant is needed (CDC 2020). Breastfed infants should be treated with chloroquine when otherwise indicated.

Infants exposed to chloroquine via breast milk should be monitored for hemolysis and jaundice, particularly premature infants or infants <1 month of age; avoid breastfeeding infants who are G-6-PD deficient (WHO 2002).

Dosage Forms: US

**Tablet, Oral:**

Generic: 250 mg [equivalent to chloroquine base 150 mg], 500 mg [equivalent to chloroquine base 300 mg]

Dosage Forms: Canada

**Tablet, Oral:**

Generic: 250 mg [equivalent to chloroquine base 150 mg]

Index Terms

Chloroquine Phosphate; Coronavirus; COVID-19

References

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Last Updated 5/1/20