Chloroquine (Lexi-Tox)

Special Alerts

Chloroquine: Coronavirus disease 2019 (COVID-19) October 2020

Most recent update(s): An emergency use authorization for chloroquine in the treatment of COVID-19 was issued by the FDA in March 2020 and subsequently revoked in June 2020 due to safety concerns and lack of efficacy (FDA 2020). National Institutes of Health (NIH) and Infectious Diseases Society of America COVID-19 guidelines recommend against the use of chloroquine, with or without azithromycin, for the treatment of COVID-19 in hospitalized patients. The NIH COVID-19 guidelines also recommend against the use chloroquine, with or without azithromycin, for the treatment of COVID-19 in nonhospitalized patients, except in the setting of a clinical trial.

As part of our response to the evolving COVID-19 pandemic, published literature and guidelines from major health organizations are continuously monitored for potential content updates. At this time, only investigational medications with data determined to be of relatively high quality and/or consistently showing positive clinical outcomes to support dosing recommendations will be included in the monograph, outside of this Special Alert field.

Further information may be found at:

ClinicalTrials.gov:
https://clinicaltrials.gov/ct2/results?cond=Covid19&term=chloroquine&cntry=&state=&city=&dist=

Hydroxychloroquine and Chloroquine Safety Alert June 2020

The FDA has revoked the emergency use authorization (EUA) from March 2020 for hydroxychloroquine and chloroquine for the treatment of COVID-19. After review of the scientific evidence available for these agents, the FDA determined hydroxychloroquine and chloroquine are unlikely to be effective in treating COVID-19; due to serious cardiac adverse events and other serious side effects, the benefits no longer outweigh the risks for authorized use.

Further information may be found at https://www.fda.gov/media/136536/download.

In addition to the benefits no longer outweighing the risks, the FDA is also warning that coadministration of chloroquine or hydroxychloroquine with remdesivir is not recommended as it may result in reduced antiviral activity of remdesivir. Health care providers should review the most up-to-date fact sheet when prescribing remdesivir.

Further information may be found at https://www.fda.gov/safety/medical-product-safety-information/remdesivir-gilead-sciences-fda-warns-newly-discovered-potential-drug-interaction-may-reduce.

Remdesivir fact sheet for health care providers: https://www.fda.gov/media/137566/download

Remdesivir fact sheet for patients and parents/caregivers:
https://www.fda.gov/media/137565/download

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 breastfeeding infant to be acceptable when used in normal maternal doses for malaria prophylaxis or treatment (CDC Yellow Book 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 Yellow Book 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).

Interim guidance is available from the Centers for Disease Control and Prevention for lactating women who are diagnosed with COVID-19 (https://www.cdc.gov/coronavirus/2019-ncov/hcp/inpatient-obstetric-healthcare-guidance.html). Information related to COVID-19 and breastfeeding is also available from the World Health Organization (https://www.who.int/docs/default-source/maternal-health/faqs-breastfeeding-and-covid-19.pdf?sfvrsn=d839e6c0_1).

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

References

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