## Hydroxychloroquine (Lexi-Tox)

Special Alerts

**Hydroxychloroquine: Coronavirus disease 2019 (COVID-19)**October 2020

Most recent update(s): An emergency use authorization for hydroxychloroquine 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 hydroxychloroquine, with or without azithromycin, for the treatment of COVID-19 in hospitalized patients. The NIH COVID-19 guidelines also recommend against the use of hydroxychloroquine, 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=hydroxychloroquine&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/136537/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: 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 Yellow Book 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). 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**:

Plaquenil: 200 mg

Generic: 200 mg

Dosage Forms: Canada

**Tablet, Oral**:

Plaquenil: 200 mg

Generic: 200 mg

Index Terms

Hydroxychloroquine Sulfate

References

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Last Updated 10/24/20