

Hydroxychloroquine (Lexi-Tox)

Special Alerts

Hydroxychloroquine: Coronavirus disease 2019 (COVID-19) Updated July 2021

Most recent update(s): **Pre-exposure prophylaxis:** The National Institutes of Health (NIH) COVID-19 guidelines recommend against the use of any drugs for SARS-CoV-2 pre-exposure prophylaxis, except in the setting of a clinical trial. **Postexposure prophylaxis:** The NIH COVID-19 guidelines recommend against the use of hydroxychloroquine for SARS-CoV-2 postexposure prophylaxis. **Treatment:** 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). [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.

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=>

IDSa: <https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/>

NIH: <https://www.covid19treatmentguidelines.nih.gov/>

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 patients; however, hydroxychloroquine is considered to be compatible for use in breastfeeding mothers with rheumatic and musculoskeletal diseases (ACR [Sammartano 2020]). Clinicians should note that when hydroxychloroquine is administered to breastfeeding patients for malaria, insufficient amounts are transferred via breast milk to provide chemoprophylaxis to the infant (CDC Yellow Book 2020).

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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