



FDA ADVISORY
No. 2020-810

MAY 13 2020

TO : **ALL HOSPITALS AND HEALTHCARE PROVIDERS**

SUBJECT : **Reminder on the Risk of QT Prolongation on the Use of Chloroquine or Hydroxychloroquine**

The Food and Drug Administration (FDA) reminds all hospitals and healthcare providers to take extreme caution on the use of Chloroquine or Hydroxychloroquine due to the risk of QT prolongation. The FDA has recorded a total of 30 cases of QT prolongation on the use of the said products from 23 March 2020 to 12 May 2020.¹

Chloroquine and hydroxychloroquine should be used with caution in patients with congenital or documented acquired QT prolongation and/or those with known risk factors for QT prolongation such as:

- Cardiac disease e.g. heart failure, myocardial infarction;
- Pro-arrhythmic conditions, e.g. bradycardia (<50 bpm);
- History of ventricular dysrhythmias;
- Uncorrected hypokalemia and/or hypomagnesemia; and
- During concomitant administration with QT interval prolonging agents e.g. Class IA and III antiarrhythmics, tricyclic antidepressants, antipsychotics, and some anti-infectives (including Azithromycin) as this may lead to an increased risk for ventricular arrhythmias, and sometimes a fatal outcome.^{2,3}

The magnitude of QT prolongation may increase with increasing concentrations of the drug. Therefore, monitoring of adverse drug reactions should be strictly implemented.

All are enjoined to report adverse drug reactions to FDA through this link: <https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH> and fill out all the required fields. For inquiries, email us at pharmacovigilance@fda.gov.ph.


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References:

1. Cases of QT prolongation on the use of chloroquine and hydroxychloroquine for the treatment of COVID-19. Retrieved from <https://vigiflow.who-umc.org/searchicrs>
2. Sanofi-Aventis, S.A. (2020). Hydroxychloroquine sulfate (Plaquenil) [package insert]
3. Avloclor 250 mg Tablets - Summary of Product Characteristics (SmPC). – (EMC). (2016, October 12). Retrieved April 20, 2020, from <https://www.medicines.org.uk/emc/product/5490/smpc>

