



## **Saudi Food & Drug Authority (SFDA) Safety Communication**

24/04/2020

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### **SFDA Recommendations for Healthcare Professionals Regarding The Unapproved Use of Hydroxychloroquine and Chloroquine in Treatment of COVID-19:**

The Saudi Food and Drug Authority (SFDA) is issuing this safety communication because of the unapproved use of hydroxychloroquine and chloroquine in treatment of coronavirus disease 2019 (COVID-19) in Saudi Arabia. At this time, no treatment has been approved or shown to be safe and effective for the treatment of COVID-19. Without enough evidence proves that the benefits of using these medications in treatment of COVID-19 outweighs their risks, the SFDA discourages the use of hydroxychloroquine or chloroquine outside of its current indications at this time other than in a clinical trial setting. Hydroxychloroquine and chloroquine are antimalarial agents. Both drugs are also approved for treatment of systemic lupus erythematosus and rheumatoid arthritis in Saudi Arabia. SFDA advises the healthcare professionals to carefully read important safety information below as well as the summary of product characteristics of hydroxychloroquine and chloroquine in particular the safety information part before prescribing these medications.

- **Important safety information about hydroxychloroquine and chloroquine for Healthcare professionals:**

- **Contraindications:**

Hydroxychloroquine and chloroquine are contraindicated in patients with known hypersensitivity to 4-aminoquinoline compounds and in the presence of retinal or visual field changes in patients. Therefore, ophthalmological examination at baseline should be performed prior to use of these medications.

- **Recommended Laboratory and Monitoring Procedure:**

A baseline ECG should be obtained to assess for QT interval prolongation and evaluation of renal and hepatic function is recommended before starting therapy of hydroxychloroquine and chloroquine.

- **Special warnings:**

**Retinopathy:** retinal damage has been observed in some patients receiving long-term treatment of hydroxychloroquine and chloroquine.

**QT interval prolongation:** use with caution in patients with cardiac disease, QT prolongation, a history of ventricular arrhythmias, bradycardia, uncorrected potassium or magnesium imbalance, and during concomitant administration with QT interval prolonging drugs such as azithromycin. Therefore, monitoring the electrocardiogram during treatment is recommended.

**Cardiomyopathy:** post marketing cases of life-threatening and fatal cardiomyopathy have been reported with use of hydroxychloroquine as well as with use of chloroquine. Therefore, clinical monitoring for signs and symptoms of cardiomyopathy is advised, including use of appropriate diagnostic tools such as ECG to monitor patients for cardiomyopathy during therapy.

**Severe hypoglycemia:** hydroxychloroquine and chloroquine have been reported to decrease insulin clearance and resistance. Loss of consciousness in patients with or without the use of antidiabetic medications has been reported.

**Hematologic effects:** hemolysis in G6PD deficient patients, pancytopenia, aplastic anemia and neutropenia have been reported during the use of hydroxychloroquine and chloroquine.

**Renal impairment:** hydroxychloroquine and chloroquine are known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function.

**Hepatic impairment:** hydroxychloroquine and chloroquine are known to concentrate in the liver. Therefore, these drugs should be used with caution in patients with hepatitis, other hepatic disease, alcoholism or in conjunction with known hepatotoxic drugs.

**Worsening of Psoriasis and Porphyria:** Use of hydroxychloroquine and chloroquine in patients with psoriasis may precipitate a severe attack of psoriasis. Also, when used these drugs in patients with porphyria, the condition may be exacerbated.

**Neuropsychiatric adverse effects:** psychosis, delirium, agitation, confusion, suicidal behavior, and hallucinations may occur with hydroxychloroquine and chloroquine phosphate.

- **Drug Interactions:**

**Digoxin:** hydroxychloroquine or chloroquine should not be co-administered with digoxin because both drugs may cause increased serum digoxin levels.

**Drugs induced QT prolongation:** hydroxychloroquine or chloroquine may prolong the QTc interval and should therefore be used with caution in patients receiving drugs known to prolong the QT interval, e.g. azithromycin, due to increased risk of ventricular arrhythmia.

**Anti-diabetic drugs:** hydroxychloroquine or chloroquine may enhance the effects of a hypoglycaemic treatment, a decrease in doses of insulin or anti-diabetic drugs may be required.

**Antacids:** antacids may reduce absorption of hydroxychloroquine and chloroquine, so it is advised that at least 4 hours between intake of these agents and hydroxychloroquine and chloroquine should be observed.

**Anti-epileptics:** hydroxychloroquine or chloroquine may increase the risk of convulsions in patients with a history of seizures. Therefore, the activity of anti-epileptic drugs might be impaired if co-administered with one of these drugs.

Finally, large clinical trials are under way to generate the robust data needed to establish the efficacy and safety of chloroquine and hydroxychloroquine in the treatment of COVID-19 in Saudi Arabia and worldwide. The SFDA will continue to support clinical trials which will enable to provide a reliable advice based on solid evidence to healthcare professionals and patients for efficacy and safety of hydroxychloroquine and chloroquine in the treatment of COVID-19.

**The SFDA urges healthcare professionals to report ADEs via any of the following contact information:**

**National Pharmacovigilance Center (NPC)**  
**Saudi Food and Drug Authority - Drug sector**  
4904 Northern ring branch rd.- Hitteen District  
Riyadh 13513 - 7148  
Kingdom of Saudi Arabia

Reporting hotline: 19999  
Email: [npc.drug@sfd.gov.sa](mailto:npc.drug@sfd.gov.sa)  
Webpage: <http://ade.sfda.gov.sa>