Saudi Food & Drug Authority (SFDA)
Safety Communication

11/05/2020

Hydroxychloroquine and Chloroquine Alone and in Combination with Azithromycin and Potential Increased Risk of Heart Rhythm Problems

The Saudi Food and Drug Authority (SFDA) would like to aware healthcare professionals who treated coronavirus disease 2019 (COVID-19) patients about the increased risk of heart rhythm problems if chloroquine or hydroxychloroquine is used alone, especially at high doses, or concomitantly with drugs induced QT prolongation such as azithromycin. Currently, no treatments, including hydroxychloroquine or chloroquine, alone or in combiation with azithromycin, have been approved for the treatment of COVID-19 in Saudi Arabia.

Hydroxychloroquine and chloroquine are antimalarial agents. Both drugs are also approved for treatment of systemic lupus erythematosus and rheumatoid arthritis in Saudi Arabia. However, at this time, both drugs, either alone or combined with azithromycin, have not been shown to be safe and effective for treating or preventing COVID-19. Therefore, the SFDA discourages the use of hydroxychloroquine or chloroquine, either alone or combined with azithromycin, outside of its current indications at this time other than in clinical trial settings.

Hydroxychloroquine and chloroquine may cause QT interval prolongation and should not be used in patients with a prolonged QT interval at baseline or at increased risk for arrythmia. Also, these drugs should be used with caution in patients with cardiac disease, history of ventricular arrhythmias, bradycardia, uncorrected potassium or magnesium imbalance, and during concomitant administration with QT interval prolonging drugs such as azithromycin because it may increase the risk of QT prolongation and ventricular arrhythmias.

The SFDA advises healthcare professionals to closely monitor patients with COVID-19 receiving chloroquine or hydroxychloroquine, either alone or combined with azithromycin, and to take into account pre-existing heart problems that can make patients more prone to heart rhythm issues. Monitoring may include ECG, electrolytes, renal function and hepatic tests. Also, Healthcare professionals should consider the potential of interacting of chloroquine or hydroxychloroquine with other medicines that cause QT prolongation even after discontinuing the medicines due to their long half-lives of approximately 30-60 days.

Finally, large clinical trials are under way to generate the robust data needed to establish the efficacy and safety of hydroxychloroquine and chloroquine in the treatment of COVID-19 in Saudi Arabia and worldwide.

The SFDA urges healthcare professionals and patients to report Adverse Drug Events (side effects) 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

Centralized number: 19999
Email: npc.drug@sfda.gov.sa
Webpage: http://ade.sfda.gov.sa
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