

Consumer Update

Feb 2022

Increased risk of Cardiovascular Events & Cardiovascular Mortality when Hydroxychloroquine or Chloroquine used with Macrolide antibiotic

EDA performs Label Update to include the following:

warnings about cases of cardiomyopathy resulting in cardiac failure, in some cases with fatal outcome. Clinical monitoring for signs and symptoms of cardiomyopathy is advised for patients taking hydroxychloroquine or long-term chloroquine. If signs and symptoms of cardiomyopathy occur during treatment with either hydroxychloroquine or chloroquine, then treatment should be stopped.

Evidence suggests both hydroxychloroquine and chloroquine can prolong the QT interval, especially in overdose or when used in combination with other medicines with the potential to induce cardiac arrhythmias. Warnings are also in place across the product information for azithromycin, clarithromycin, and erythromycin to use caution in patients with a history of QT interval prolongation or in patients receiving a medicine known to cause QT prolongation.

Background:

An observational study has shown that co-administration of azithromycin with hydroxychloroquine in patients with rheumatoid arthritis is associated with an increased risk of cardiovascular events (including angina or chest pain and heart failure) and cardiovascular mortality

carefully consider the benefits and risks before prescribing systemic azithromycin or other systemic macrolide antibiotics (erythromycin or clarithromycin) to patients being treated with hydroxychloroquine or chloroquine

if there is a clinical need to prescribe systemic macrolide antibiotics with hydroxychloroquine or chloroquine, use caution in patients with risk factors for cardiac events and follow advice in the product information for each medicine

be vigilant for psychiatric reactions associated with hydroxychloroquine or chloroquine, especially in the first month of treatment; events have been reported in patients with no prior history of psychiatric disorders

References: *MHRA* ([Click here](#))