



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 May 2020
EMA/282511/2020

COVID-19: reminder of the risks of chloroquine and hydroxychloroquine

EMA is reminding healthcare professionals to closely monitor patients with COVID-19 who are receiving chloroquine or hydroxychloroquine, given the serious side effects that can result from treatment with these medicines.

Both chloroquine and hydroxychloroquine, which are authorised for malaria and certain autoimmune diseases, have been used to treat patients with COVID-19 but their beneficial effects in this patient population are not established.

Several observational studies have reported that chloroquine and hydroxychloroquine are associated with an increased risk of heart problems, a well-known side effect of such treatments, including cardiac arrhythmias and cardiac arrest.

When prescribing these medicines, healthcare professionals should take into account pre-existing heart conditions, uncorrected potassium or magnesium imbalance, and concomitant use with medicines that prolong the QT interval as these factors may make patients more prone to heart rhythm disorders.

Healthcare professionals should also note that heart rhythm disorders may be more likely or be more severe if chloroquine or hydroxychloroquine are used at higher doses than those recommended for their authorised indications or if they are combined with certain antibiotics such as azithromycin. EMA has previously [communicated on these risks](#).

In addition to their effects on the heart, these medicines may cause neuropsychiatric disorders, including agitation, insomnia, confusion, psychosis and suicidal ideation. These medicines are also known to affect the liver, cause neuronal damage that can lead to seizures (fits), and lower blood sugar.

In view of the emerging data, some EU countries have suspended or stopped clinical trials investigating chloroquine and hydroxychloroquine in COVID-19 patients. For some trials, including WHO's large multinational [Solidarity](#) trial, enrolment of patients to trial arms with these medicines has been suspended. A preliminary review of the [Recovery](#) trial, a large ongoing study on COVID-19 patients, did not identify reasons to suspend or stop the trial.

EMA reiterates that while further analyses of available data are being carried out, chloroquine and hydroxychloroquine should only be used in clinical trials for treatment or prophylaxis of COVID-19 or in national emergency use programmes in hospitalised patients under close supervision. It is important



that properly designed, randomised clinical trials can be completed, with adjustments as needed, to generate the necessary evidence on benefits and risks of these medicines in COVID-19.

Patients who have been prescribed chloroquine or hydroxychloroquine for authorised indications (malaria and certain autoimmune diseases such as rheumatoid arthritis and lupus) should continue to take their medicines as advised by their doctor. Patients who have any questions about their treatment should talk to their doctor or pharmacist.

EMA and the national competent authorities are closely monitoring medicines used in the treatment of COVID-19 and will continue communicating and take action as new information emerges. In addition, EMA continues to collaborate and share information with the WHO and international regulators.

Patients and healthcare professionals are reminded to report any suspected side effects to their [national regulatory authorities](#).

This EMA public health statement has been issued by the COVID-19 [EMA pandemic Task Force \(COVID-ETF\)](#).