
Reminder of potential risk of serious side effects associated with the use of chloroquine and hydroxychloroquine in the context of COVID-19 pandemic

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Information on chloroquine and hydroxychloroquine

- Chloroquine and hydroxychloroquine are currently authorised to treat malaria and certain immune diseases
- Chloroquine and hydroxychloroquine are currently being used in the context of the ongoing pandemic for treating patients with COVID-19. They are also being investigated in clinical trials

Information from the EMA about side effects associated with chloroquine and hydroxychloroquine

Chloroquine and hydroxychloroquine are known to potentially cause side effects such as heart rhythm problems, liver and kidney problems, nerve cell damage that can lead to seizures (fits) and low blood sugar (hypoglycaemia). Heart rhythm problems can be potentially exacerbated if treatment with chloroquine or hydroxychloroquine is combined with other medicines, having similar side effects on the heart, such as azithromycin, particularly when taken at high doses. Use of these products in COVID-19 pandemic should be carried out in line with national clinical protocols and clinical supervision.

Clinical trials are being carried out to investigate the use of chloroquine and hydroxychloroquine in the context of COVID-19 pandemic. Clinical data are still very limited and inconclusive and the beneficial effects of these medicines in COVID-19 have not been demonstrated. Results from large, well-designed studies are needed to make more robust conclusions.

The EMA together with national competent authorities are monitoring the situation closely and have enhanced their safety monitoring of medicines used in the treatment of COVID-19 in order to take timely action when necessary.

In Malta

For Healthcare Professionals

- Healthcare professionals are recommended to closely follow COVID-19 national guidelines and recommendations

- Large, randomised clinical trials are looking at the benefits and risks of chloroquine and hydroxychloroquine in patients with COVID-19. In the context of COVID-19, these medicines should only be used as part of clinical trials or in line with nationally agreed protocols. They must not be used without a prescription and without supervision by a doctor.

For more information please see the European Medicines Agency's [Chloroquine and Hydroxychloroquine press release](#).

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on chloroquine and hydroxychloroquine. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form and sending it to Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or online to <http://www.medicinesauthority.gov.mt/adrportal> or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate Medicines Authority

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Feedback Form

The Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this form (address side up), stapling the ends and then posting (no stamp required)

Feedback:

We thank you for your interest and look forward to hearing your opinion.

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Pharmacovigilance Section

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