

## **COVID-19: chloroquine and hydroxychloroquine only to be used in clinical trials or emergency use programmes**

Chloroquine and hydroxychloroquine, two medicines currently authorized for malaria and certain autoimmune diseases, are being investigated worldwide for their potential to treat coronavirus disease (COVID-19). However, efficacy in treating COVID-19 is yet to be shown in studies.

It is very important that patients and healthcare professionals only use chloroquine and hydroxychloroquine for their authorised uses or as part of clinical trials or national emergency use programmes for the treatment of COVID-19.

Both chloroquine and hydroxychloroquine can have serious side effects, especially at high doses or when combined with other medicines. They must not be used without a prescription and without supervision by a doctor; prescriptions should not be given outside their authorised uses except in the setting of a clinical trial or nationally agreed protocols.

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. EMA welcomes these trials, which will enable authorities to give reliable advice based on solid evidence to healthcare professionals and patients.

Considering the urgency and the pressure healthcare systems face to save lives during the COVID-19 pandemic, some countries, including the USA and France, have put strict protocols in place to allow the experimental use of these two medicines, for example, in patients with severe forms of COVID-19.

Chloroquine and hydroxychloroquine are vital medicines for patients with auto-immune conditions such as lupus. It is important that such patients are still able to obtain them and do not face shortages caused by stockpiling or use outside the authorised indications. In some countries, prescribing of the medicines has been restricted to reduce the risk of shortages.

Information for patients:

- Only use chloroquine or hydroxychloroquine if they have been prescribed for you and a doctor is supervising your treatment.
- Ask your doctor or pharmacist if you have any questions about the use of chloroquine or hydroxychloroquine or any other medicine.

Information for healthcare professionals:

- For COVID-19, chloroquine and hydroxychloroquine should preferably be used in the context of clinical trials. Outside clinical trials, they can be used in accordance with national established protocols.
- Chloroquine and hydroxychloroquine should continue to be used in chronic conditions. In order to prevent unnecessary strain on supply chains, patients should only receive their usual supply of medicines. Healthcare professionals should not write prescriptions that cover more than the usual duration.

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