# Sanofi: Important Information on Plaquenil® and COVID-19

**LAVAL, APRIL 17, 2020** – There has been increased media coverage around the off-label use of hydroxychloroquine in the management of COVID-19 based on preliminary results from independent studies from different countries. The situation is raising many questions from our different stakeholders.

**Patient safety is the priority**

**To date there is insufficient clinical evidence to draw any conclusions over the clinical efficacy or safety of hydroxychloroquine (or chloroquine) in the management of COVID-19. The preliminary results from different independent studies require further analysis and more robust and larger clinical studies to assess the patient benefit/risk profile of Plaquenil® in COVID-19.**

Today, in Canada Plaquenil® (hydroxychloroquine) is indicated for:

- the treatment of rheumatoid arthritis, and discoid and systemic lupus erythematosus, in patients who have not responded satisfactorily to drugs with less potential for serious side effects.
- the suppressive treatment and treatment of acute attacks of malaria due to P. vivax, P. malariae, P. ovale, and susceptible strains of P. falciparum

**Any use of this medicine in the management of COVID-19 is an off-label use (i.e. in absence of a marketing authorization for the indication of COVID-19 even when national or provincial guidance/recommendations have been issued).**

**Ensure supply continuity**

One of our top priorities is to ensure supply continuity for use of Plaquenil® in the current indications.

Sanofi is working with local health authorities and scientific experts in different countries impacted by the outbreak in order to investigate the patient benefit/risk profile of Plaquenil® (hydroxychloroquine) in the treatment of COVID-19.

**For medical information or questions:** Please contact the Sanofi Canada Medical Information Helpline from 8:00 to 18:00 EST: 1-800-265-7927.

**IMPORTANT SAFETY REMINDER ABOUT PLAQUENIL®**

PLAQUENIL® (hydroxychloroquine sulfate tablets) is indicated for:

- the treatment of rheumatoid arthritis, and discoid and systemic lupus erythematosus, in patients who have not responded satisfactorily to drugs with less potential for serious side effects.
- the suppressive treatment and treatment of acute attacks of malaria due to P. vivax, P. malariae, P. ovale, and susceptible strains of P. falciparum.

The main side effects of hydroxychloroquine are described in the Product Monograph. At the recommended daily dose for approved indications, ranging from 200 to 400 mg (without exceeding 800 mg at treatment onset) daily in adults for chronic treatment of autoimmune indications, or up to 2000mg maximum administered over 3 days in acute treatment of malaria, the most serious side effects of hydroxychloroquine are eye disorders following long term use, including retinopathy, with changes in pigmentation and visual field defects and severe hypoglycemia including loss of consciousness (in patients treated with and without antidiabetic medications). Cardiotoxic effects are rare but serious complications of hydroxychloroquine, which include acute cardiac conduction disorders (QT prolongation, ventricular arrhythmia) have also been observed. Neurological, hepatic, severe skin disorders, allergic reactions have also been described.

**Hydroxychloroquine should be used with caution in patients receiving drugs known to prolong the QT interval such as some anti-infectives, e.g. macrolides including azithromycin, due to an increased risk of ventricular arrhythmia.**

The risk and severity of side-effects may increase with a higher posology (dosage) of hydroxychloroquine.

Healthcare professionals should consult the current Product Monograph for the most up to date safety information. Patients taking hydroxychloroquine-containing medicines, like any other medicines, should follow

the instructions provided in the Patient Medication Information.

**Patients must not take Plaquenil® without medical prescription or advice.** They should always consult with their healthcare professionals.

**Sanofi also requests that all off-label use be communicated to the Sanofi Canada pharmacovigilance team via the Sanofi Canada Medical Information Helpline from 8:00 to 18:00 EST at 1-800-265-7927or to Health Canada at canada.ca/medeffect or by phone 1-866-234-2345, whether or not the patients suffer adverse events.**

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