News Releases

Update on Plaquenil® (hydroxychloroquine)

Canadians should not take any drug without medical advice and only use a medication for the treatment of the condition for which it was prescribed.

There has been increased media coverage around the off-label use of Plaquenil® (hydroxychloroquine) in the management of COVID-19 based on preliminary results from independent studies from different countries.

To date there is insufficient clinical evidence to draw any conclusions over the clinical efficacy or safety of hydroxychloroquine in the management of COVID-19, both in the prevention or as treatment. The preliminary results from different independent pilot studies require further analysis and larger clinical studies are being conducted to assess the patient benefit/risk profile of Plaquenil® in COVID-19.

Our priority is to ensure patient safety. Globally, we are engaged in the ongoing international effort around hydroxychloroquine and to find out whether it is well-tolerated and effective in COVID-19 patients. For more information, please visit Sanofi.com.

Plaquenil® (hydroxychloroquine) is approved in Canada **only for use** in 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. It is also indicated for 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 considered an off-label use (i.e., in absence of a marketing authorization for the indication of COVID-19). Healthcare Professionals should report adverse reactions, off-label use, overdose and medication errors in accordance with Health Canada regulations.

IMPORTANT SAFETY REMINDER ABOUT PLAQUENIL®

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 based on body weight (and without exceeding 1550 mg base in adults) 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, hypoglycemia 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 is communicated to the Sanofi Canada pharmacovigilance team at 1-800-589-6215 or canada.pharmacovigilance@sanofi.com**, whether or not the patients suffer adverse events.**