Sanofi: Important Information on hydroxychloroquine and COVID-19

MANILA, 29 MAY 2020 – There has been increased media coverage around the off-label use of hydroxychloroquine in the management of COVID-19. The situation is raising many questions from our different stakeholders.

Patient safety is the priority

To date there is insufficient clinical evidence to draw definite conclusions over the clinical efficacy or safety of hydroxychloroquine in the management of COVID-19.

Today, in the Philippines, hydroxychloroquine is registered in

> Adults
> Treatment of rheumatoid arthritis, discoid and systemic lupus erythematosus, and dermatological conditions caused or aggravated by sunlight.
>
> Pediatric population
> Treatment of juvenile idiopathic arthritis (in combination with other therapies), discoid and systemic lupus erythematosus.

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 guidance/recommendations have been issued).

Ensure supply continuity

One of our top priorities is to ensure supply continuity for use of hydroxychloroquine in the current indications. We are already putting supply efforts in place to address the increasing demand of the product and significantly increase our production capacity.

Given the current situation, we understand that patients who need hydroxychloroquine sulfate for chronic rheumatologic and dermatological diseases may have concerns about the availability of their medicine.

For medical information or questions: Please contact the Sanofi Philippines Medical Information Helpline medinfo.ph@sanofi.com.

IMPORTANT SAFETY REMINDER ABOUT HYDROXHYCHLOROQUINE

The main side effects of hydroxychloroquine are described in the product information. At the recommended daily dose for approved indications, ranging from 200 to 400 mg (without exceeding 6.5mg/kg of ideal body weight daily in adults for the treatment of rheumatoid arthritis, discoid and systemic lupus erythematosus, and dermatological conditions caused or aggravated by sunlight, 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 and psychiatric, 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 Halofantrine, other arrhythmogenic drugs due to an increased risk of cardiac conduction disorders.

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

Healthcare professionals should consult the current Summary of Product Characteristics 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 Information Leaflet.

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

Sanofi is asking Health Authorities in all relevant countries to communicate a clear position regarding current lack of robust clinical data for the use of hydroxychloroquine, in the management of COVID-19, emphasizing that such use will be off-label, and to communicate the known serious adverse reactions associated with hydroxychloroquine, namely the contraindications in patients with known hypersensitivity to 4-aminoquinoline compounds; with pre-existing maculopathy of the eye; below 6 years of age (200mg tablets not adapted for weight <35 kg) and the risk of retinal toxicity, hypoglycemia and cardiac toxicity as well as the known risk of interactions.

Sanofi also requests that all off-label use is communicated to the Sanofi affiliate pharmacovigilance team [PV.Philippines@sanofi.com**] or the national spontaneous reporting system [**pharmacovigilance@fda.gov.ph**], whether or not the patients suffer adverse events.**