PRESSEMELDING

Sanofi: Important Information on Plaquenil® and COVID-19

Lysaker, Norway, 20th April 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 Norway, Plaquenil® (hydroxychloroquine) is registered for the following indications: Adults: Malaria therapy and -prophylaxis. Reumatoid rthritis. Lupus erythematosus. Sjøgren's syndrom. Light dermatosis. Children >31 kg: Malaria therapy and -prophylaxis.

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 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 and, if requested by the local governments and / or health authorities, to provide the product to the extent that it can.

For medical information or questions: Please contact the Sanofi Norway Medical Information Helpline from 10:00-14:00, phone number: 46 91 80 01 or medinfo-norge@sanofi.com

IMPORTANT SAFETY REMINDER ABOUT PLAQUENIL®

Plaquenil® (hydroxychloroquine) is registered for the following indications: Adults: Malariatherapy and -prophylaxis. Reumatoid arthritis. Lupus erythematosus. Sjøgren's syndrom. Light dermatosis. Children >31 kg: Malaria therapy and -prophylaxis.

Adverse reactions:
Very common (≥1/10): Gastrointestinal: Stomach pain, nausea. *Common (≥1/100 to <1/10):* Gastrointestinal: Diarrhea, vomiting. Skin: Rash, pruritus. Nevrological: Headache.

Psychic: Affect lability. Metabolism/nutrition: Anorexia. Eye: Blurred vision due to accommodation disorders (related to dosage, reversible). *Uncommon (≥1/1000 to <1/100):* Skin: Pigmentation changes in skin and mucosa, faded hair colour, hair loss. Liver/bile: Abnormal liver function tests. Muscle-skeleton system: Sensoric/motoric disease. Nevrological: Dizziness. Psychic: Nervousness. Ear: Vertigo, ringing in the ears. Eye: Retinopathy with changes in pigmentation and vision defects (apparently reversible if early discontinuation). Retina changes can initially be asymptomatic, or can give scotomatic vision with paracentral, pericentral rings, passing scotoma, abnormal colour vision.

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 600 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 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 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 Plaquenil® without medical prescription or advice. They should always consult with their healthcare professionals.

Sanofi is asking local Health Authorities to communicate a clear position regarding current lack of robust clinical data for the use of Plaquenil®, in the management of COVID-19, emphasizing that such use will be off-label, and to communicate the known serious adverse reactions associated with Plaquenil®, 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. Please contact the Sanofi Norway Medical Information Helpline from 10:00 – 14:00, phone number: 46 91 80 01 or medinfo-norge@sanofi.com or the national spontaneous reporting system, whether or not the patients suffer adverse events, https://legemiddelverket.no/bivirkninger-og-sikkerhet/meld-bivirkninger