

Safety Alert

May 2024

Hydroxychloroquine Sulfate– Risk of drug-induced phospholipidosis, hepatotoxicity, hepatitis B virus reactivation and aggravation of myasthenia gravis

EDA performs label update to include the following:

4.4 Special warnings and precautions for use

Hepatotoxicity

Serious cases of drug-induced liver injury (DILI) including hepatocellular injury, cholestatic liver injury, acute hepatitis, mixed hepatocellular/cholestatic liver injury and fulminant hepatic failure (including fatal cases) have been reported during use of Plaquenil. Risk factors may include pre-existing liver disease, or predisposing conditions such as uroporphyrinogen decarboxylase deficiency or concomitant hepatotoxic medications. Prompt clinical evaluation and measurement of liver function tests should be performed in patients who report symptoms that may indicate liver injury. For patients with significant liver function abnormalities

Hepatitis B reactivation

Reactivation of hepatitis B virus has been reported in patients treated with hydroxychloroquine in combination with other immunosuppressants.

Drug Induced Phospholipidosis

Cases of Hydroxychloroquine induced phospholipidosis have been reported during use of Plaquenil. Drug-induced phospholipidosis may occur in different organ systems such as cardiac, renal, or muscle. Monitoring for toxicity is advised. Discontinue Plaquenil if cardiac, renal, or muscle toxicity related to drug induced phospholipidosis is suspected or demonstrated by tissue biopsies.

4.8 Undesirable effects

- Cases of hydroxychloroquine induced phospholipidosis have been reported. Drug-induced phospholipidosis may occur in different organ systems such as cardiac, renal, or muscle causing toxicity.

Background:

4.1 Therapeutic indications

Adults

hydroxychloroquine tablets are recommended for the treatment of rheumatoid arthritis, discoid and systemic lupus erythematosus, and dermatological conditions caused or aggravated by sunlight.

Paediatric Population

Treatment of juvenile idiopathic arthritis (in combination with other therapies), discoid and systemic lupus erythematosus

References:

Health Canada ([Click here](#))