

Consumer Update

Apr 2021

Hydroxychloroquine Risk of Sweet's Syndrome and Severe Cutaneous Adverse Reactions (SCARS)

EDA performs Label Update to include the following:

Warnings

skin reaction including plum-colored, raised, painful sores, particularly on your arms, hands, fingers, face and neck, which may also be accompanied by fever. This could be a condition called Sweet syndrome

Side effects

Sweet's syndrome and SCARS

Background:

Severe cutaneous adverse reactions (SCARs) Cases of severe cutaneous adverse drug reactions (SCAR), including drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP), Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported during treatment with hydroxychloroquine.

Patients with serious dermatological reactions may require hospitalization, as these conditions may be life-threatening and may be fatal.

If signs and symptoms suggestive of severe skin reactions appear, hydroxychloroquine should be withdrawn at once and alternative therapy should be considered.

Serious skin rashes have been reported with the use of Hydroxychloroquine. Frequently, the rash can involve ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These serious skin rashes are often preceded by flu-like symptoms such as fever, headache and body ache. The rash may progress to widespread blistering and peeling of the skin. If you develop these skin symptoms, stop taking hydroxychloroquine and contact your doctor immediately

References: EMA ([Click here](#))