



Direct Healthcare Professional Communication

June 2022

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

Dear Healthcare Professional,

The Egyptian Pharmaceutical Vigilance Center of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following:

Summary

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- If signs and symptoms suggestive of severe skin reactions appear, hydroxychloroquine should be withdrawn at once and alternative therapy should be considered.

Background information on the security concerns

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.

Healthcare professionals shall advice patients to:

Stop taking Hydroxychloroquine and see a doctor straight away if you notice any of the following severe skin reactions as you may need urgent medical treatment:

- rash with a fever and flu-like symptoms and enlarged lymph nodes. This could be a condition called Drug Reaction with Eosinophilia and Systemic Symptoms
- blistering, widespread scaly skin, pus-filled spots together with fever. This could be a condition called Acute Generalized Exanthematous Pustulosis (AGEP).
- blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms





and fever. This could be a condition called Stevens-Johnson syndrome (SJS)

- multiple skin lesions, itching of the skin, joint aches, fever and a general ill feeling. This could be a condition called Toxic Epidermal Necrolysis (TEN)
- 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's syndrome

Hydroxychloroquine indication

Hydroxychloroquine is indicated for treatment of rheumatoid arthritis, systemic lupus erythematosus, and dermatological conditions aggravated by sunlight.

References

EMA

https://www.ema.europa.eu/en/documents/psusa/hydroxychloroquine-cmdh-scientific-conclusions-grounds-variation-amendments-product-information/00001693/202104_en.pdf

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: Egyptian Pharmaceutical Vigilance Center

Address: 21 Abd El Aziz Al Soud Street, El-Manial, Cairo, Egypt, And PO Box: 11451 Telephone: +202- 25354100, Extension: 1470 Fax: +202 - 23610497

Email: pv.followup@edaegypt.gov.eg

Online reporting: <https://primaryreporting.who-umc.org/EG>

QR Code:

Hotline: 15301

