Direct Healthcare Professional Communication

February 2022

Olsalazine – Severe cutaneous adverse reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP)

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

- The FDA recently updated olsalazine label to include the risk of severe cutaneous adverse reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP).
- There have been post-marketing reports of severe cutaneous adverse reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP) associated with olsalazine administration.
- Patients should discontinue olsalazine at the first signs or symptoms of severe cutaneous adverse reactions or other signs of hypersensitivity and consider further evaluation.

Further information on the safety concern:

Olsalazine is indicated for the maintenance of remission of ulcerative colitis in adult patients who are intolerant of sulfasalazine.

Severe cutaneous adverse reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP) reported with use of olsalazine, discontinuation of therapy at first signs or symptoms of severe cutaneous adverse reactions or other signs of hypersensitivity is recommended.

Severe cutaneous adverse reactions (SCARs) represent an uncommon but potentially life-threatening form of delayed T cell-mediated reaction. The spectrum of illness ranges from acute generalized exanthematous pustulosis (AGEP) to drug reaction with eosinophilia with systemic symptoms (DRESS), to the most severe form of illness, Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN).

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The product information (summary of product characteristics (SmPC) and package leaflet (PL)) for Motilsalin will be updated to include new warnings on severe cutaneous adverse reactions.

Recommendations for Healthcare Professionals:

- Patients should discontinue olsalazine at the first signs or symptoms of severe cutaneous adverse reactions or other signs of hypersensitivity and consider further evaluation.
- Patients should be advised to contact their doctor if signs or symptoms of severe cutaneous adverse reactions or other signs of hypersensitivity occurred.

References

FDA

https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/index.cfm?event=searchdetail.page&DrugNameID=2343

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

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