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Kigali; 18/03/2022
Ref N°: DIS/1395./FDA/2022

# MEDICINE SAFETY COMMUNICATION

**Medicine: SOFOSBUVIR**

**RE: Warning on the potential risk of severe cutaneous adverse reactions (SCAR) in patients using Sofosbuvir**

Reference is made to the new safety information on Sofosbuvir published in the WHO Pharmaceuticals Newsletter - N° 02/2021 warning on the potential risk of severe cutaneous adverse reactions (SCAR) following use of Sofosbuvir. Further reference is made to the review conducted by Health Canada on the potential risk of severe cutaneous adverse reactions (SCAR) following the use of Sofosbuvir, triggered by an update to the product safety information made by the European Medicines Agency (EMA).

Sofosbuvir is a drug candidate for Hepatitis C treatment and a nucleotide analog that is a highly potent inhibitor of the NS5B polymerase (non-structural proteins essential for viral RNA replication that is a valuable target for directly acting antiviral agents (DAAs)) in Hepatitis C Virus (HCV). It has shown high efficacy in combination with several other drugs against HCV due to its high potency, low side effects, oral administration, and high barrier to resistance.

Rwanda FDA warns about the potential risk of severe cutaneous adverse reactions (SCAR) in patients using Sofosbuvir. There is a risk of developing life-threatening reactions of specific types of SCAR namely Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), acute generalized exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS), erythema multiforme (EM), and bullous dermatitis (BD).

Cont

**Information to Healthcare professionals**

- Pharmacists are encouraged to provide detailed medical information to patients and encourage them to report any cutaneous adverse reactions encountered.
- Physicians must use Sofosbuvir with caution and consider withholding or discontinuing this drug in patients with such severe dermatologic manifestations.
- Dermatologists and Physicians are advised to recognize drug reactions early for further therapeutic actions.
- Mild and moderate cases improve with topical medications and supportive treatment, the severe and life-threatening cases also require permanent discontinuation of therapy.

**Information to patients**

- Patients are warned about the potential risk of severe cutaneous adverse reactions (SCAR) for Sofosbuvir-users.
- Patients are advised to report any Sofosbuvir-induced cutaneous adverse reactions to health professionals or Rwanda FDA.

**Information to Marketing Authorization Holders**

- Marketing Authorization Holders are advised to update the safety information for Sofosbuvir to include the risk of SCAR including Stevens-Johnson syndrome (SJS).

**Note:** Patients and Healthcare Professionals are urged to report any suspected serious adverse drug reactions associated with Sofosbuvir and other medicines to Rwanda FDA by completing ADR/AEFI reporting form accessible on the Rwanda FDA website via the link https://www.rwandafda.gov.rw/fileadmin/user_upload/RwandaFDA/Publications/Pharmacovigilance___Food_Safety_Monitoring/Forms/ADR_AEFI_Reporting_form.pdf and the filled form should be sent to the email: pv_sm@rwandafda.gov.rw

Sincerely,

18/3/20

**Dr. Emile BIENVENU**
**Director General**

**References**


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