



**RWANDA FDA**  
Rwanda Food and Drugs Authority

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Kigali, 118 NOV 2019  
Ref N° 1531 /Rwanda FDA/2019

**RWANDA FDA SAFETY COMMUNICATION: DIS/CRC/003**

**Medicine: Amoxicillin**

**Re: Risk of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) syndrome associated with Amoxicillin.**

Referring to the new safety information published in the WHO Pharmaceuticals NEWSLETTER NO.5/2018, further reference also is made to the European Medicines Agency (EMA)'s Pharmacovigilance Risk Assessment Committee (PRAC) recommendations. Medicines containing Amoxicillin and Amoxicillin/Clavulanate were reported to be associated with a very rare risk of drug reaction with eosinophilia and systemic symptoms (DRESS)

Amoxicillin is indicated for the treatment of commonly occurring bacterial infections such as respiratory tract, genitourinary, skin, and soft tissues infections. Drug reaction with eosinophilia and systemic symptoms (DRESS) is a rare, potentially life-threatening, drug-induced hypersensitivity reaction that includes skin eruption, hematologic abnormalities (eosinophilia, atypical lymphocytosis), lymphadenopathy, and internal organ involvement (liver, kidney, lung)

Rwanda FDA urges patients and health care professionals to report any suspected serious adverse drug events such as eosinophilia and systemic symptoms (DRESS) involving Amoxicillin and or other drugs to Rwanda FDA by completing ADR/AEFI reporting form accessible on Rwanda FDA website on the link

[http://www.rwandafda.gov.rw/web/fileadmin/adr\\_aefi\\_reporting\\_form.pdf](http://www.rwandafda.gov.rw/web/fileadmin/adr_aefi_reporting_form.pdf) and the filled form should be sent to the email: [pv\\_sm@rwandafda.gov.rw](mailto:pv_sm@rwandafda.gov.rw) and copy to [info@rwandafda.gov.rw](mailto:info@rwandafda.gov.rw)

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Sincerely,



**Dr. Charles KARANGWA**  
**Ag. Director General of Rwanda FDA**



## **References**

1. The Health Sciences Authority (HSA), *Risk of drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome*, Product Safety Alerts, HSA, 14 September 2018 (<http://www.hsa.gov.sg/>)
2. Musa Sharkawi, A Curious Manifestation of Amoxicillin-Induced DRESS Syndrome, 2014 Accessible on [https://journal.chestnet.org/article/S0012-3692\(16\)50039-7/fulltext](https://journal.chestnet.org/article/S0012-3692(16)50039-7/fulltext)
3. Abhishek Deet al, Drug reaction with eosinophilia and systemic symptoms: An update and review of recent literature, 2018 accessible on <http://www.e-ijd.org/article.asp?issn=0019-5154;year=2018;volume=63;issue=1;spage=30;epage=40;aulast=De>