Ref. N°: DD/PVCT/ 3628 /FDA /2025

SAFETY INFORMATION COMMUNICATION

[Medical Product category]	Title
Acyclovir	**Warning on potential risk of drug reaction with eosinophilia and systemic symptoms (DRESS).**

1. Introduction

Reference is made to regulations governing pharmaceutical products and medical devices, especially Article 23 on safety information and communication.
Referring to the safety information published in WHO Pharmaceuticals Newsletters No.5,2024, further reference is also made to the South African Health Products Regulatory Authority (SAHPRA), which has informed healthcare professionals about the risk of drug reaction with eosinophilia and systemic symptoms (DRESS) associated with the use of acyclovir.

2. Description

Acyclovir is a new antiviral drug that acts as a specific inhibitor of herpesvirus DNA polymerase. The Drug is indicated for the treatment of initial and recurrent herpes simplex infections of the skin and mucous membranes, including genital herpes simplex virus infections, in both immunocompetent and immunocompromised patients. It is also indicated for the treatment of herpes zoster (shingles) if the lesions are not older than 72 hours, as well as other related syndromes.

The drug may be administered topically to the skin, intravenously, orally, or topically to the eye (only topical and intravenous preparations are currently available). DRESS, also known as drug-induced hypersensitivity syndrome (DIHS), is a rare, but serious, and potentially life-threatening fatal drug reaction, characterised by symptoms which include widespread rash, high body temperature, liver enzyme elevations, elevated white blood cell count (including eosinophils), enlarged lymph nodes, and possibly other body organs involvement. The symptoms of DRESS typically appear within two weeks to two months after starting treatment with acyclovir. The available data from literature and post-marketing reports provide sufficient evidence that corroborates the association of acyclovir and the risk of DRESS.

The most important step in the management of DRESS is early diagnosis and immediate cessation of the suspected offending drug. Patients with DRESS syndrome should be managed in an intensive care setup for appropriate supportive care and infection control.

It is against this background that Rwanda FDA warns about the Drug reaction with Eosinophilia and Systemic Symptoms (DRESS) associated with the use of Acyclovir.

3. *Information for the Patients and Caregivers*

- Patients should be aware of rare side effects of Acyclovir, like DRESS syndrome.
- Patients should immediately report to their healthcare professionals when they experience a skin eruption while taking Acyclovir.
- Patients should follow instructions: Use as directed by a healthcare professional or according to the product label.

4. *Information to Healthcare Professionals*

Healthcare professionals are therefore required to:

- Be vigilant about the potential risk of life-threatening DRESS following Acyclovir treatment.
- Educate patients to closely monitor for serious skin reactions and advise them to seek urgent medical attention when they experience signs and symptoms such as fever, severe rash, peeling skin, swelling of the face, swollen lymph glands, flu-like feeling, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feeling thirsty, urinating less often, or less urine.
- If DRESS is suspected, discontinue Acyclovir immediately and refer the patient to a dermatologist for diagnosis and treatment.
- In patients who develop DRESS while receiving Acyclovir, do not restart Acyclovir treatment at any time and consider an alternative treatment.
- Report all suspected adverse events associated with Acyclovir to the Rwanda FDA.

5. *Information for the Marketing Authorization Holders/Manufacturers*

Rwanda FDA is requesting Marketing Authorization Holders to submit an updated SmPC for Acyclovir to include the risk of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) as an adverse drug reaction. The product label and/or packaging label should also be updated to remind healthcare professionals of the potential effects of Acyclovir.

6. *Reporting channel*

Patients and Healthcare Professionals are urged to report any suspected adverse drug event/reaction associated with Acyclovir or any other medical product to Rwanda FDA by using an online reporting tool (VigiMobile for medicines), which is available on the Rwanda FDA Website at *https://vigiflow-eforms.who-umc.org/rw/adr* or using online reporting system (PViMS) accessible on *https://pvims.rwandafda.gov.rw/security/landing*.

Sincerely,

RWANDA FOOD AND DRUGS AUTHORITY - RWANDA FDA

Prof. Emile BIENVENU
Director General

7. *References*

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