



## Rwanda Food and Drugs Authority

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### **SAFETY INFORMATION COMMUNICATION**

Medicine	Safety information
Diuretics including Acetazolamide	Warning on potential risk of eye disorders

#### ***1. Introduction***

Reference is made to the law N° 003/2018 of 09/02/2018 establishing Rwanda FDA, and determining its mission, organization and functioning with a mandate to protect the public health;

Reference is made to the new safety information on Diuretics including Acetazolamide published in the WHO Pharmaceuticals Newsletter - N° 02/2021 warning on the potential risk of eye disorders <sup>7</sup> and signal assessment reports by Rwanda FDA

Further reference to the Drug safety Update published by National Pharmaceutical Regulatory Agency (NPRA) of Malaysia on risk of Choroidal Effusion, Acute Myopia & Acute Angle-Closure Glaucoma.

Considering the assessment conducted by Health Canada on the risk of the choroidal effusion (CE), acute myopia (AM) and acute angle-closure glaucoma (AACG) linked with the use of Diuretics or Acetazolamide.<sup>3</sup> Idiosyncratic reactions resulting in Choroidal Effusion with visual defect, transient myopia and AACG are linked with sulfonamide derivative drugs and diuretics.

#### ***2. Description of the safety information***

Diuretics include Loop diuretics, Thiazide diuretics, Potassium-sparing diuretics, carbonic anhydrase inhibitors, Osmotic diuretics, and Vasopressin receptor antagonists.<sup>3</sup> They are indicated to treat oedema and to lower high blood pressure and act primarily by blocking reabsorption of sodium at four major sites in the nephron. <sup>2</sup>As for Acetazolamide, which has diuretic properties, is a carbonic anhydrase inhibitor appropriate for the treatment of glaucoma, selected cases of epilepsy, salicylate overdosage and abnormal retention of fluids

Choroidal effusion is an abnormal fluid accumulation in the space between the sclera and the choroid. It commonly occurs as a complication of glaucoma surgery. However, it may also arise due to other conditions, including trauma, inflammatory and infectious diseases, neoplasms, venous congestion as well as drug reactions.

The exact pathophysiology of how these diuretics can cause choroidal effusion, acute myopia, or acute angle-closure glaucoma has not been fully elucidated. Therefore, they are described as idiosyncratic reactions. In most literature, the sulfonamide moiety of these DRUGS is postulated of causing these ocular disorders.

607

Rwanda FDA warns about the risk of eye disorders in patients using Diuretics including Acetazolamide. No local cases of choroidal effusion, acute myopia or acute angle-closure glaucoma following the use of these diuretics have been reported to Rwanda thus far.<sup>4i9u8</sup>

There is risk of developing choroidal effusion (CE), acute myopia (AM) and acute angle-closure glaucoma (AACG).

### **3. Information to Consumers/Patients/Caregivers**

- Patients are warned about the risk of eye disorders linked with the use of Diuretics including Acetazolamide.
- Patients are advised to report any Diuretics- induced choroidal effusion (CE), acute myopia (AM) and/or acute angle-closure glaucoma (AACG) to health professionals and Rwanda FDA.
- Patients are informed about possible experience of a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in the eye and can happen within hours to weeks of taking diuretics.

### **4. Information to Healthcare Professionals**

- Be vigilant on the risk of choroidal effusion, acute myopia, and acute angle-closure glaucoma with sulfonamide diuretics use, especially in patients with risk factors including a history of sulfonamide or penicillin allergy.
- Avoid using acetazolamide in cases of sulfonamide-induced angle closure glaucoma given potential cross-reactivity and exacerbation of the underlying process.
- Avoid using acetazolamide in cases of sulfonamide-induced angle closure glaucoma given potential cross-reactivity and exacerbation of the underlying process.
- Report all suspected adverse events associated with products containing hydrochlorothiazide, chlorthalidone, indapamide and acetazolamide to the Authority.

### **5. Information to Manufacturers/Marketing Authorization Holders**

Marketing Authorization Holders of diuretics (such as Hydrochlorothiazide, Chlorthalidone, Indapamide) and Acetazolamide are advised to update the safety information by adding a warning about the risks of choroidal effusion (CE), acute myopia (AM) and acute angle-closure glaucoma (AACG) as follows:


- Talk to your doctor, pharmacist, or nurse before taking any diuretics.
- If you experience a decrease in vision or eye pain, these could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion), acute angle-closure glaucoma; or an increase of pressure in your eye and can happen within hours to weeks of taking.

### **6. Reporting Channel**

Patients and Healthcare Professionals are urged to report any suspected serious adverse drug reactions associated with Diuretics including Acetazolamide, and other medicines to Rwanda FDA. By completing ADR/AEFI reporting form accessible on Rwanda FDA website via the link [https://rwandafda.gov.rw/wp-content/uploads/2022/11/ADR\\_AEFI\\_Reporting\\_form.pdf](https://rwandafda.gov.rw/wp-content/uploads/2022/11/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).

Sincerely,

*E. Bienvenu*  
09/02/2024



**Prof. Emile BIENVENU**

## 7. References

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