

Ref. N°: DD/PVCT/4416 /FDA /2025

SAFETY INFORMATION COMMUNICATION

Medical Product category	Title
Bilastine (oral formulations)	Risk of QT prolongation /Torsade de points.

1. Introduction

Reference is made to the regulations governing pharmaceutical products and medical devices, including IVDs, especially in Article 23 on safety information and communication.

Reference is also made to the safety information published in WHO Pharmaceuticals Newsletters No.3,2025(1). Further reference is also made to the Health Products Regulatory Authority (HPRA) of Ireland, which has announced that the product information for bilastine (oral formulations) will be updated to include the risk of QT prolongation and Torsade de points (a type of polymorphic ventricular tachycardia)(2).

Following a routine review of available post-marketing safety data from clinical trials and spontaneous cases, EMA's Pharmacovigilance Risk Assessment Committee (PRAC) determined that electrocardiogram QT prolongation is not sufficiently recognized as a risk associated with oral bilastine use. The PRAC therefore recommended that a warning about QT prolongation, Torsades de Pointes, and related risk factors should be included in the product information for bilastine oral formulations. In this regard, Rwanda FDA warns about the risk of QT prolongation and Torsades de Pointes associated with the use of bilastine (oral formulations).

2. Description

Bilastine is a specific, prolonged-action second-generation H1-receptor antagonist. Initially authorized in the European Union in 2010, it is used to manage symptoms of allergic rhinoconjunctivitis and urticaria. Bilastine is a non-sedating, long-acting histamine antagonist with selective peripheral H1 receptor antagonist affinity and no affinity for muscarinic receptors. Bilastine inhibited histamine-induced wheal and flare skin reactions for 24 hours following single doses(3).

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It is a BCS class II drug with an absolute oral bioavailability of 60.67%, which decreases by approximately 30% due to food-drug interactions in the presence of food(4). Patients who are at increased risk include patients with a history of cardiac arrhythmias; patients with hypokalaemia, hypomagnesaemia, hypocalcaemia; patients with known prolongation of the QT interval or significant bradycardia; and patients with concomitant use of other medicinal products associated with QT/QTc-prolongation. It is against this background that the Rwanda FDA recommends the following:

3. Information for the Patients and Caregivers

- Most people take bilastine safely, but the risk is higher if you already have heart problems, low potassium/magnesium, or are taking other medicines that affect heart rhythm.
- Always take bilastine exactly as prescribed. Higher doses increase the risk.
- Tell your doctor/pharmacist about all medicines, especially if you are taking:
 - a) Antiarrhythmics (for heart rhythm problems)
 - b) Certain antibiotics (e.g., macrolides, fluoroquinolones)
 - c) Antifungal medicines (e.g., ketoconazole, itraconazole)
 - d) Medicines for depression or mental health conditions (some antipsychotics, antidepressants)
- Tell your doctor if you have:
 - a) A history of fainting, irregular heartbeat, or family history of sudden cardiac death.
 - b) Electrolyte disturbances (low potassium, magnesium, calcium).
 - c) Kidney or liver disease.
- Stop taking bilastine and get immediate medical attention if you experience:
 - a) Fast, pounding, or irregular heartbeat
 - b) Fainting or severe dizziness
 - c) Shortness of breath or chest discomfort

4. Information to Healthcare Professionals

- Caution should be exercised when administering bilastine to patients who are at increased risk of experiencing QT/QTc-prolongation,
- This includes patients with a history of cardiac arrhythmias; patients with hypokalemia, hypomagnesaemia, hypocalcaemia; patients with known prolongation of the QT interval or significant bradycardia; and patients with concomitant use of other medicinal products associated with QT/QTc-prolongation.
- Electrocardiogram QT prolongation has also been reported post-marketing.

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- Healthcare professionals are urged to report any adverse drug reactions (ADRs) associated with the use of Bilastine (oral formulations) to Rwanda FDA via the VigiMobile application available on Rwanda FDA website.

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

Rwanda FDA is requesting Marketing Authorization Holders to submit an updated SmPC for Bilastine (oral formulations) medicines to include the Risk of QT prolongation /Torsade de points. The product label and/or box warning should also be updated to remind healthcare professionals of the potential effects of Bilastine (oral formulations).

6. *Reporting channel*

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

Sincerely,



Prof. Emile BIENVENU

Director General

7. *References*

1. WHO. WHO Pharmaceuticals 2025. 2025;(1):1–13.

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4. Oudah SA, Al-Khedairy EBH. Development and characterization of bilastine nanosuspension for enhanced dissolution in orodispersible films. OpenNano [Internet]. 2025;21(October 2024):100230. Available from: <https://doi.org/10.1016/j.onano.2024.100230>

