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SAFETY INFORMATION COMMUNICATION

Medical Product	Title
Cetirizine, levocetirizine	Risk of severe itching after discontinuation of long-term use.

1. Introduction

Reference is made to the safety information published in WHO Pharmaceuticals Newsletters No.3, 2025(1), further reference is made to the US Food and Drug Administration (FDA) communication warning patients that stopping the oral allergy medicines cetirizine (Zyrtec®) or levocetirizine (Xyzal®) after long-term use may lead to experiencing rare but severe itching, also called pruritus(2).

It is against this background that Rwanda FDA warns about the Risk of severe itching after discontinuation of long-term use associated with the use of cetirizine, levocetirizine.

2. Description

Cetirizine and levocetirizine are antihistamines that block a molecule called histamine that the body releases during allergic reactions. Both medicines are approved to treat seasonal allergies, called seasonal allergic rhinitis, in adults and children 2 years and older(3). The medicines are also approved to treat year-round allergies, called perennial allergic rhinitis, and chronic hives, called chronic idiopathic urticaria, in patients 6 months and older(4). Long-term use of Cetirizine and levocetirizine, may lead to the body's histamine receptors (H1R) or regulatory systems adaptation to the constant blockade. Sudden removal of receptor blockade might lead to a temporary imbalance or rebound effect where histamine or related inflammatory responses become more active than before, triggering widespread itching(5). Long-term treatment with antihistamines can decrease H1R gene expression to the basal level(6). It is hypothesized that after stopping long-term treatment, H1R blockade disappears relatively fast (the half-life of (levo)cetirizine is 6–10 h). In the presence of histamine, this can lead to occupancy of the H1R and because the number of H1R was down-regulated owing to long-term treatment, a relatively high percentage of H1R will be occupied with histamine, possibly resulting in itch(5).

Therefore, as part of risk management and minimization Rwanda FDA recommends the following:

3. Information for the Patients and Caregivers

- Contact your health care professional if you develop severe itching after stopping prescription or OTC cetirizine or levocetirizine.
- Know that itching typically occurs within a few days of stopping these medicines after daily use for a few months to years.
- If you are planning on using cetirizine or levocetirizine long term, especially for more than a few months, should discuss the benefits and risks with your health care professional, who can provide advice based on your personal needs.



4. *Information to Healthcare Professionals*

- Discuss the risk of severe itching after stopping cetirizine or levocetirizine with patients when prescribing or recommending these medicines, especially if planned for chronic use, and with those who indicate they are using over-the-counter (OTC) versions.
- Advise patients to contact you if they experience severe itching after stopping cetirizine or levocetirizine.
- Always report any adverse events related to cetirizine and levocetirizine to Rwanda FDA for further analysis and regulatory actions.

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

Rwanda FDA is notifying Marketing Authorization Holders to submit an updated SmPC for Cetirizine, levocetirizine to include the Risk of severe itching after discontinuation of long-term use. The product label and/or box warning should also be updated to remind healthcare professionals of the potential effects of Cetirizine, levocetirizine.

6. *Reporting channel*

Patients and healthcare professionals are urged to report any suspected adverse drug event/reaction associated with Cetirizine, levocetirizine 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 online reporting system (PViMS) accessible on <https://pvims.rwandafda.gov.rw/security/landing>

Sincerely,

Prof. Emile BIENVENU
Director General

E. Bienvenu
07 Jan 2026



7. References

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