SFDA
Safety communication

[15/06/2025]

Risk of Severe Pruritus After Discontinuation of Cetirizine or Levocetirizine.

The Saudi Food and Drug Authority (SFDA) would like to notify healthcare professionals about a safety concern associated with the use of cetirizine and levocetirizine. Emerging global pharmacovigilance data have identified rare but severe cases of pruritus (itching) occurring after the abrupt discontinuation of long-term use of these medicines.

Cetirizine is a potent and selective antagonist of peripheral H1-receptors. Levocetirizine, the (R) enantiomer of cetirizine shares a similar pharmacological profile. Both agents are indicated for symptomatic treatment of seasonal and perennial allergic rhinitis and urticaria. For locally registered products, healthcare professionals can refer to the SFDA Drug List.

Cases of pruritus have been reported globally following the discontinuation of long-term use of cetirizine or levocetirizine. These cases demonstrate a consistent temporal relationship, with symptoms typically emerging within 1 to 5 days of stopping treatment, particularly among individuals who had used the medicines for several months or longer. In most cases, pruritus was widespread and severe, significantly impacting patients' quality of life. However, restarting the medicine often relieved pruritus.

SFDA Recommendations for Healthcare Professionals:

- Inform patients about the potential risk of developing severe pruritus after stopping long-term cetirizine or levocetirizine therapy, especially if used continuously for several months.
- Advise patients not to discontinue treatment abruptly without medical supervision.
- Evaluate unexplained pruritus in patients with a history of recent discontinuation of these medicines, considering the possibility of rebound pruritus.
- In cases where treatment discontinuation is necessary, consider a gradual tapering strategy.

- Educate patients that reinitiating therapy may relieve symptoms and tapering off the medicine after restarting it, though evidence on effective treatment options for this condition remains limited.

Call for reporting:

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA using the following contact information:

The National Pharmacovigilance Centre (NPC):

Call Center: 19999

Website: https://ade.sfda.gov.sa

SFDA RMM Webpage: