



Direct Healthcare Professional Communication

December 2021

Levocetirizine shouldn't be used in children less than 2 years

Dear Healthcare Professional,

The Egyptian Pharmaceutical Vigilance Center of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following:

Summary

- Levocetirizine shouldn't be used in children less than 2 years.
- Clinical data is insufficient to support the application of Levocetirizine in infants and young children under 2 years.

Background information

- Levocetirizine is an oral anti-histaminic indicated for the symptomatic treatment of allergic rhinitis (including persistent allergic rhinitis) and urticaria in adults and children aged 6 years and above as Tablets, and for the symptomatic treatment of allergic rhinitis (including persistent allergic rhinitis) and urticaria in adults and children aged 2 years and above as oral drops, solution/oral solution
- Based on the review of the data on safety and efficacy, the benefit-risk balance of Levocetirizine dihydrochloride containing medicinal products is no longer authorized for the treatment of pediatric patients aged < 2 years.
- Levocetirizine, the (R) enantiomer of cetirizine, is a potent, selective, peripheral H₁ - Receptor antagonist. Binding studies have shown that levocetirizine has a high affinity for human H₁ receptors has (K_i = 3.2 nmol / l). The affinity of levocetirizine is therefore twice as high as that of cetirizine (K_i = 6.3 nmol / l). Levocetirizine dissociates from the H₁ receptors with a half-life of 115 ±38 min. The receptor occupancy of levocetirizine was 90% after 4 hours after a single application and 57% after 24 hours. In pharmacodynamic studies in healthy volunteers, levocetirizine has been shown in only half the dose of cetirizine both on the skin and in the nose with cetirizine has a comparable effect.
- Nevertheless, the product information should-be updated to contraindicate use in pediatric patients aged <2 years.

References

EMC

<https://www.medicines.org.uk/emc/product/8568/smpc>





Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: Egyptian Pharmaceutical Vigilance Center

Address: 21 Abd El Aziz Al Soud Street, El-Manial, Cairo, Egypt, And PO Box: 11451 Telephone:
+202- 25354100, Extension: 1470 Fax: +202 – 23610497

Email: pv.followup@edaegypt.gov.eg

Online reporting: <https://primaryreporting.who-umc.org/EG>

QR Code:

Hotline: 15301

