General Administration for Pharmaceutical Vigilance





جمهورية مصر العربية هيئة الدواء المصرية الإدارة المركزية للرعاية الصيدلية الإدارة العامة لليقظة الصيدلية

Direct Healthcare Professional Communication

February 2022

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 H 1 Receptor antagonist. Binding studies have shown that levocetirizine has a high affinity for human H 1 receptors has (Ki = 3.2 nmol / l). The affinity of levocetirizine is therefore twice as high as that of cetirizine (Ki = 6.3 nmol / l). Levocetirizine dissociates from the H 1 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

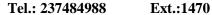
https://www.medicines.org.uk/emc/product/8568/smpc







21st Abdel-Aziz Al-Saud, Manial Al-Roda, Cairo



The Arab Republic of Egypt **Egyptian Drug Authority**

Central Administration for Pharmaceutical Care

General Administration for Pharmaceutical Vigilance





جمهورية مصر العربية هيئة الدواء المصرية الإدارة المركزية للرعاية الصيدلية الإدارة العامة لليقظة الصيدلية

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



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