



Vistaril® (hydroxyzine), Xyzal® (levocetirizine) – Safety Communication

- On November 8, 2016, the [FDA approved](#) a new update to the *Precautions* section of the [Vistaril \(hydroxyzine pamoate\)](#) drug label pertaining to the risk of acute generalized exanthematous pustulosis (AGEP).
- A similar update was [FDA approved](#) and added to the post-marketing section of the [Xyzal \(levocetirizine\)](#) drug label.
- Vistaril is indicated for the following:
 - Symptomatic relief of anxiety and tension associated with psychoneurosis and as an adjunct in organic disease states in which anxiety is manifested.
 - Management of pruritus due to allergic conditions such as chronic urticaria and atopic and contact dermatoses, and in histamine-mediated pruritus.
 - As a sedative when used as premedication and following general anesthesia.
- Xyzal is indicated for the following:
 - Relief of symptoms associated with seasonal allergic rhinitis in adults and children ≥ 2 years of age
 - Relief of symptoms associated with perennial allergic rhinitis in adults and children ≥ 6 months of age
 - Treatment of the uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children ≥ 6 months of age
- Hydroxyzine may rarely cause AGEP, a serious skin reaction characterized by fever and numerous small, superficial, non-follicular, sterile pustules, arising within large areas of edematous erythema.
 - Patients should be informed about the signs of AGEP, and discontinue hydroxyzine at the first appearance of a skin rash, worsening of pre-existing skin reaction which hydroxyzine may be used to treat, or any other sign of hypersensitivity.
 - If signs and symptoms suggest AGEP, use of hydroxyzine should not be resumed and alternative therapy should be considered.
 - Cetirizine or levocetirizine should be avoided in patients who have experienced AGEP or other hypersensitivity reactions with hydroxyzine, due to the risk of cross-sensitivity.



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