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.