AMERICAN HEALTH CARE

DRUG PRODUCTS & SAFETY NEWS

Xolair Expanded Indication

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The U.S. Food and Drug Administration (FDA) has approved an expanded indication for Xolair (omalizumab) injection. Indication now includes treatment for patients 6 years and older with moderate and severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. Previously, this medication was approved for the treatment of asthma, and idiopathic urticarial in patients 12 years and older.

Healthcare professionals and patients are encouraged to report any adverse events or side effects related to the use of this product and/or quality problems to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- ✓Complete and submit the report online: www.fda.gov/MedWatch/report.htm
- ✓Complete and return a form by mail (address on the pre-addressed form) or fax (1-800-FDA-0178).

[Call 1-800-332-1088 to request a reporting form or download a form at http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm.]

Source: Facts and Comparisons

For additional information: http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/103976s5225lbl.pdf