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# AAP News

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*AAP News* originally published online September 26, 2014;

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# AAP News

**Breaking News**

September 26, 2014

[www.aapnews.org](http://www.aapnews.org)

## FDA warns of increased risks of asthma drug Xolair

Patients receiving the asthma medication Xolair (omalizumab) may have a slightly higher risk of serious adverse events affecting the cardiovascular and cerebrovascular systems, according to a review by the Food and Drug Administration (FDA). In addition, there are uncertain findings on a potential cancer risk.

The FDA has added information about these risks to the drug label. In 2009, the FDA issued an early communication about ongoing safety evaluations of Xolair but didn't recommend any label changes at that time.

The injectable asthma drug is indicated for patients ages 12 years and older with moderate to severe persistent allergic asthma when symptoms are not controlled by inhaled corticosteroids.

New FDA guidance for health care professionals related to Xolair includes the following:

- Periodically reassess the need for continued therapy with this medication based on the patient's disease severity and level of asthma control.
- The appropriate duration of therapy for chronic idiopathic urticaria has not been evaluated. Again, periodically reassess the need for continued use of Xolair.
- Advise patients not to decrease the dose or stop taking the drug or any other asthma medicines unless their health care professional instructs them to do so.
- Provide and instruct patients to read the Xolair medication guide before beginning treatment and before starting each new prescription (<http://www.fda.gov/downloads/Drugs/DrugSafety/UCM089829.pdf>).

Read the FDA safety alert, which includes resource links, at <http://1.usa.gov/1CtM8Av>.

Adverse reactions or problems experienced with the use of this product should be reported to the FDA at <http://1.usa.gov/1m1XxgQ> or by calling 800-332-1088.

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