

Special Interest Articles:

- New ADHD Medications
- Flud
- Xolair



Did you know?

The CDC influenza activity trends show that the 2016-17 season lasted from October 2, 2016, to May 20, 2017 with low activity through November and increased activity in December. The number of patients peaked in February. A total of 98 laboratory-confirmed deaths occurred among children.

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Two New ADHD Medications for 2017

Shire Pharmaceuticals announced that it would begin distribution of Mydayis™, a new treatment option of mixed salts of amphetamine, while Neos Therapeutics plans to launch Cotelma XR-ODT™ (methylphenidate extended release orally disintegrating tablet) in the fall of 2017.

Mydayis is approved for Attention Deficit Hyperactivity Disorder (ADHD) in patients 13 years and older. The effects will last up to 16 hours, therefore eliminating the need for a second dose of ADHD medicine. Mydayis is available in once-a-day doses of 12.5, 25, 30 and 37.5 mg. Pediatric patients 12 years and

younger experienced higher plasma concentrations and higher rates of adverse reactions, mainly insomnia and decreased appetite, than patients 13 years and older taking the same dose.

Cotelma XR-ODT will be dispensed in a child resistant blister pack and features a slow release methylphenidate. Cotelma XR-ODT is the first and only extended-release orally disintegrating methylphenidate tablet for the treatment of ADHD in patients 6-17 years of age. In a Phase 3 clinical trial in children, onset of effect was evident at one hour post dose and lasted through 12 hours.

References

1. Mydayis [package insert]. Shire. Lexington, MA.2017. <http://www.mydayis.com/>. (Accessed August 29, 2017).
2. Cotelma XR-ODT [package insert]. Neos Therapeutics. Grand Prairie, TX. 2017. <https://www.cotemplaxrodthep.com/#isi>. (Accessed August 29, 2017).

Flud™ Flu Vaccine with Adjuvant for Adults 65+

CDC studies conducted during previous flu seasons estimate that 80 to 90 percent of seasonal flu-related deaths and 50-70 percent of hospitalizations occur among people 65 years of age and older. Flud™ is a licensed seasonal influenza (flu) vaccine containing adjuvant for adults 65 years of age and older. An adjuvant is an ingredient added to a vaccine to create a stronger immune response to vaccination. The adjuvant, MF59, is a squalene based oil-in-water emulsion. MF59 is added to the vaccine to boost immune response. Studies in humans and animals suggest that MF59 recruits

immune cells to the injection site and enhances their uptake of antigen. Flud is an alternative to Fluzone High-Dose and the standard flu shot.



References

1. *Influenza. Pharmacist's Letter. October 2016; Vol 32.*
2. Seasonal Influenza-Different Flu Vaccines. Centers for Disease Control and Prevention. July 11, 2016.(Accessed August 29, 2017).
3. Flud™ [package insert]. Seqirus. Holly Springs, NC.2015. [https:// http://hcp.flud.com/hcp/clinical-overview](https://http://hcp.flud.com/hcp/clinical-overview).(Accessed August 29, 2017).

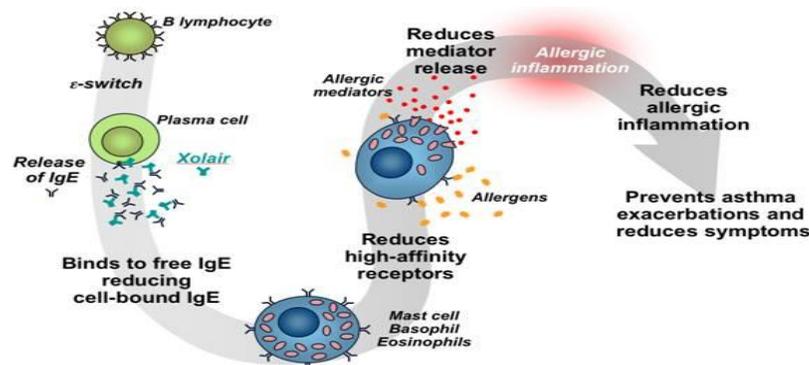
Xolair® Immunosuppressant for Allergic Asthma and Chronic Idiopathic Urticaria

Xolair (omalizumab) is a recombinant DNA-derived humanized IgG1 κ monoclonal antibody that selectively binds to human immunoglobulin E (IgE). Xolair is produced by a Chinese hamster ovary cell suspension culture in a nutrient medium that also contains the antibiotic gentamicin. Gentamicin is not measurable in the final product. Xolair is contained in a single use vial that is reconstituted with sterile water and administered as a subcutaneous injection. Xolair should be given by a healthcare provider, in a healthcare setting. Xolair is given in one or more injections every two to four weeks. In asthma patients, a blood test for IgE must be performed prior to starting Xolair to determine the appropriate dose and dosing frequency.

Xolair is indicated for patients 6 years of age and older with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to allergens that are airborne, such as pollen and spores, and whose symptoms are inadequately controlled with inhaled corticosteroids. Xolair has been shown to decrease the incidence of asthma exacerbations in these patients. Xolair is also indicated for the treatment of adults and adolescents 12 years of age and older with chronic idiopathic urticaria that remains symptomatic despite H1 antihistamine treatment.

Omalizumab inhibits the binding of IgE to the high-affinity IgE receptor (Fc ϵ RI) on the surface of mast cells and basophils. Reduction in surface-bound IgE on Fc ϵ RI-bearing cells limits the degree of release of mediators of the allergic response. Treatment with Xolair also reduces the number of Fc ϵ RI receptors on basophils in atopic patients. In Chronic Idiopathic Urticaria (CIU), omalizumab binds to IgE and lowers free IgE levels. Subsequently, IgE receptors (Fc ϵ RI) on cells down-regulate. The mechanism, by which an improvement of CIU symptoms is seen, is unknown.

“In asthma patients, a blood test for IgE must be performed prior to starting Xolair to determine the appropriate dose and dosing frequency.”



A case-control study showed that, among Xolair users, patients with a history of anaphylaxis to foods, medications, or other causes, were at increased risk of anaphylaxis associated with Xolair compared to those with no prior history of anaphylaxis. In postmarketing reports, the frequency of anaphylaxis attributed to Xolair use was estimated to be at least 0.2% of patients based on an estimated exposure of about 57,300 patients from June 2003 through December 2006. The more common reported side effects included injection site reactions, headache, and nasopharyngitis. Anaphylaxis presenting as bronchospasm, hypotension, syncope, urticaria and/or angioedema of the throat or tongue, has been reported to occur after administration of Xolair. Anaphylaxis has occurred as early as after the first dose of Xolair, but also has occurred beyond one year after beginning regularly administered treatment. The FDA requires a boxed warning with administration of Xolair. Malignant neoplasms were observed in 20 of 4127 (0.5%) Xolair-treated patients compared with 5 of 2236 (0.2%) control patients in clinical studies of adults and adolescents \geq 12 years of age with asthma and other allergic disorders.

The maximum tolerated dose of Xolair has not been determined. Single intravenous doses of up to 4,000 mg have been administered to patients without evidence of dose limiting toxicities. The highest cumulative dose administered to patients was 44,000 mg over a 20 week period, which was not associated with toxicities.

References

1. Black Box Warning for Xolair. Pharmacist's Letter. July 2016.
2. Pulmonary-Allergy Drugs Advisory Committee Meeting. U.S. Food & Drug Administration. https://www.fda.gov/ohrms/dockets/ac/03/briefing/3952B1_01_Genentech-Xolair.htm. May 15, 2003. (Accessed August 28, 2017).
3. Xolair® [package insert]. Genentech. San Francisco, CA. 2017. https://www.gene.com/download/pdf/xolair_prescribing.pdf (Accessed August 28, 2017).