OVERVIEW
Omalizumab

Introduction

Omalizumab is a monoclonal antibody to human immunoglobulin E (IgE), which leads to a decrease in IgE binding to mast cells and basophils and a reduction in allergic symptoms of asthma and seasonal rhinitis. Omalizumab therapy has not been associated with serum enzyme elevations during therapy and has yet to be implicated in cases of clinically apparent drug induced liver injury with jaundice.

Background

Omalizumab (oh" ma liz' ue mab) is a recombinant, human monoclonal antibody to IgE which binds avidly to circulating immunoglobulin E, preventing its attachment to high affinity receptors on mast cells and basophils. This receptor inhibition prevents the release of histamine and other mediators of the allergic immune response, reducing airway inflammation and spasm and alleviating symptoms of asthma and allergic rhinitis. Therapy with omalizumab has been shown to reduce the requirement for inhaled corticosteroids and lower the frequency of exacerbations of asthma and to decrease the severity and symptoms of chronic urticaria of unknown cause. Omalizumab was approved for use in the United States in 2003 for therapy of patients with severe and persistent asthma despite corticosteroid inhalation therapy. The indications were extended in 2014 to include chronic idiopathic urticaria. Omalizumab has been evaluated in patients with seasonal rhinitis, but has yet to be approved for that use. Omalizumab is available in single use vials of 150 mg under the brand name Xolair. The recommended dose is 150 to 300 mg intravenously every 4 weeks or 225 to 375 mg every 2 weeks based upon body weight and IgE levels. Common side effects include injection site reactions, rash, diarrhea, nausea and vomiting and epistaxis. Rarely, omalizumab can cause serious acute anaphylaxis or anaphylactoid reactions (~ 0.1%) and should be given under close medical supervision.

Hepatotoxicity

In large clinical trials, omalizumab was not associated with changes in serum aminotransferase levels during therapy, and rates of most adverse reactions were similar in patients who received omalizumab or placebo. There have been no published reports of clinically apparent acute liver injury attributed to omalizumab therapy. Thus, liver injury from omalizumab must be very rare, if it occurs at all.

Mechanism of Injury

Omalizumab is a human monoclonal antibody and is unlikely to be inherently hepatotoxic. While most recombinant proteins are metabolized by the liver, the metabolism leads largely to small peptides and

amino acids which may be reused to synthesize proteins and are unlikely to be toxic or immunogenic. Omalizumab lowers serum levels of IgE, which seems to have no adverse effects on the liver and does not result in significant immunosuppression.

Drug Class: Antiasthmatic Agents, Monoclonal Antibodies

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PRODUCT INFORMATION
Omalizumab

REPRESENTATIVE TRADE NAMES

Omalizumab – Xolair®

DRUG CLASS

Antiasthmatic Agents

COMPLETE LABELING

Product labeling at DailyMed, National Library of Medicine, NIH

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CHEMICAL FORMULA AND STRUCTURE
Omalizumab

DRUG	CAS REGISTRY NO.	MOLECULAR FORMULA	STRUCTURE
Omalizumab	242138-07-4	Monoclonal Antibody	Not Available