

OMALIZUMAB - FLASH CARD

Compilation by- Dr Sivasankari M, Dr Gautam Kumar Singh
IADVL TASKFORCE ON BIOLOGICALS AND SMALL MOLECULES

Mechanism of Action

- Recombinant murine derived humanized monoclonal antibody targeting human Immunoglobulin E (IgE)

Indications

FDA approved

- Chronic spontaneous urticaria

Off-label

- Chronic inducible urticaria: CINDU
- Bullous pemphigoid
- Mastocytosis
- Urticarial vasculitis
- Atopic dermatitis
- Kimura's disease
- Hyper IgE syndrome

Dosage

- Chronic urticaria - Administer omalizumab 300 mg every four weeks .
- 150 mg every four weeks can also be given . Discontinuation of this molecule does not cause rebound of free IgE; Total IgE levels gradually returns to baseline levels within a year.

Mode of administration: Subcutaneous.

Omalizumab should only be administered by a physician or trained health care professional in a setting where any episode of anaphylaxis can be managed.

An observation period of 2 hours for the first three injections and 30 minutes for subsequent injections has been recommended to watch for features of anaphylaxis.

Reconstitution:

- 1.4 ml of water for injection needs to be reconstituted with the lyophilised powder to form 1.2 ml viscous solution containing 150mg of Omalizumab.
- It takes 15 to 20 min to dissolve completely.

Contra-indication

- Hypersensitivity to Omalizumab

SPECIAL CONSIDERATIONS

- No dose adjustment required in cases of renal or liver impairment
- Can be given in Elderly and children >12 years
- Pregnancy – Cat B drug (benefits outweigh risk)
- Lactation – not much studies. Not advisable.

Adverse effects

- Injection site reactions
- Viral infections
- Nasopharyngitis
- Upper respiratory tract infection
- Sinusitis and
- Headache are common.
- Anaphylaxis has been noted in about 0.2% of patients.

Pre work-up

- Complete blood count and hemogram
- Erythrocyte sedimentation rate or C-reactive protein
- Liver function test
- Renal function test and urinalysis
- Serum electrolytes
- Anti-nuclear and anti-dsDNA antibodies
- Screening for hepatitis and HIV infection (Tuberculosis screening/ Serum IgE are not mandatory)

Monitoring

- Platelet count

Availability and average cost

- 150 mg lyophilised powder for reconstitution in single dose vial and 150mg/ml single dose prefilled syringes.
- 8000 to 11000 Rs per vial