Safety Alert May 2025

Sugammadex -risk of serious Hypersensitivity Reaction

EDA performs label update to include the following:

Undesirable effects
Description of selected adverse reactions
In postmarketing reports, hypersensitivity has been observed for sugammadex as well as for sugammadex-rocuronium complex

Background:

Therapeutic Indication:

Therapeutic indications Reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults. For the paediatric population: sugammadex is only recommended for routine reversal of rocuronium induced blockade in paediatric patients from birth to 17 years

Hypersensitivity:

Hypersensitivity as an immunological dysfunction is defined as exaggerated or inappropriate response of the immune system, which is mostly targeted at innocuous antigens with consequent tissue damage. Hypersensitivity can be classified into four types; namely, type I (Immediate), type II (antibody-mediated), type III (immune complex-mediated), and type IV (cell-mediated or delayed-type) hypersensitivity.

Type I hypersensitivity or allergy, the most common immune disorder, is mainly mediated by immunoglobulin (Ig)E and mast cells. It can cause anaphylaxis, food allergy, and asthma.

Type II hypersensitivity can lead to tissue damage by three main mechanisms: direct cellular destruction (e.g., autoimmune hemolytic anemia and immune thrombocytopenia), inflammation (e.g., Goodpasture's syndrome and acute rheumatic fever), and disrupting cellular function (e.g., myasthenia gravis and Graves' disease).

Type III hypersensitivity is caused by excess production of immune complexes or impaired clearance of them and includes serum sickness, systemic lupus erythematosus, and post-streptococcal glomerulonephritis.

Type IV hypersensitivity is mediated by T cells and macrophages, causing diseases like multiple sclerosis and rheumatoid arthritis. In this chapter, we explained the underlying mechanism of action of each type of hypersensitivity and provided definition, epidemiological and clinical features, diagnostic methods, and treatments for disorders caused by each mechanism.

References:
EMA (Click here)