

GAMMAGARD S/D

[Immune Globulin Intravenous (Human)]

IgA less than 1 µg/mL in a 5% solution

INDICATION

GAMMAGARD S/D is indicated for the treatment of primary immunodeficiency disorders associated with defects in humoral immunity. These include but are not limited to congenital X-linked agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

GAMMAGARD S/D must not be used in patients with selective IgA deficiency (IgA < 0.05 g/L) where the IgA deficiency is the only abnormality of concern.

IMPORTANT RISK INFORMATION

Patients may experience severe hypersensitivity reactions or anaphylaxis in the setting of detectable IgA levels following infusion of GAMMAGARD S/D.

Immune Globulin Intravenous (Human) products have been reported to be associated with renal dysfunction, acute renal failure, osmotic nephrosis, and death. Patients predisposed to acute renal failure include patients with any degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Especially in such patients, IGIV products should be administered at the minimum concentration available and the minimum rate of infusion practicable. While these reports of renal dysfunction and acute renal failure have been associated with the use of many of the licensed IGIV products, those containing sucrose as a stabilizer accounted for a disproportionate share of the total number.

GAMMAGARD S/D does not contain sucrose.

GAMMAGARD S/D, IgA <1 µg/mL, has a lower IgA concentration than GAMMAGARD S/D which has a concentration of 1 to 2.2 µg/mL. IGIV preparations depleted of IgA (0.4 to 2.9 µg/mL) were shown to be better tolerated by a limited number of patients who reacted to IGIV preparations with higher IgA concentrations. However, the concentration of IgA that will not provoke a reaction is not known, and therefore all IGIV preparations carry the risk of inducing an anaphylactic reaction to IgA. In such instances, a risk of anaphylaxis may exist despite the fact that GAMMAGARD S/D, IgA <1 µg/mL, contains trace amounts of IgA.

GAMMAGARD S/D is made from human plasma. It may carry a risk of transmitting infectious agents, e.g. viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

Aseptic meningitis syndrome (AMS) has been reported to occur infrequently in association with IGIV treatment. Discontinuation of IGIV treatment has resulted in remission of AMS within several days without sequelae.

Certain components used in the packaging of GAMMAGARD S/D contain natural rubber latex.

IGIV products can contain blood group antibodies that may cause a positive direct antiglobulin reaction and, rarely, hemolysis.

Thrombotic events have been reported in association with IGIV. Patients at risk may include those with a history of atherosclerosis, multiple cardiovascular risk factors, advanced age, impaired cardiac output, and/or known or suspected hyperviscosity, hypercoagulable disorders, and prolonged periods of immobilization.

Various minor reactions, such as mild to moderate hypotension, headache, fatigue, chills, backache, leg cramps, lightheadedness, fever, urticaria, flushing, slight elevation of blood pressure, nausea and vomiting may occasionally occur.

Please review the enclosed GAMMAGARD S/D [Immune Globulin Intravenous (Human)], IgA less than 1 µg/mL in a 5% solution Prescribing Information for full prescribing details.