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Intravenous Immune Globulin (IVIg)

A newly approved therapeutic option for the treatment of adult dermatomyositis

DESCRIPTION: Dermatomyositis (DM) is a rare chronic systemic autoimmune disease with a characteristic skin rash and progressive proximal muscle weakness. In this Zoom webinar, you will get an opportunity to learn about Octapharma's IVIg therapy and the results of the landmark Progress in Dermatomyositis (ProDERM) study. The successful ProDERM Study resulted in the first and only FDA-approved IVIg therapy for DM in adults.

Myositis Support & Understanding and Octapharma USA are proud to co-sponsor this exciting educational program. We look forward to having you join us!

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Presented by:
Rohit Aggarwal, MD, MS



Rheumatology
Professor of Medicine
Medical Director, Arthritis
and Autoimmunity Center
Sub-Specialty Education
Coordinator
Division of Rheumatology
Department of Medicine

www.understandingmyositis.org



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octapharma

octagam® 10%

Immune Globulin Intravenous (Human) 10% Liquid Preparation

Indications and Important Safety Information

Indications

Octagam 10% is an immune globulin intravenous (human) liquid preparation indicated for the treatment of dermatomyositis (DM) in adults. Octagam 10% is also indicated for the treatment of chronic immune thrombocytopenic purpura (ITP) to rapidly raise platelet counts to control or prevent bleeding in adults.

Contraindications

Octagam 10% is contraindicated in patients who have a history of severe systemic hypersensitivity reactions, such as anaphylaxis, to human immunoglobulin. Octagam 10% contains trace amounts of IgA (average 106 µg/mL in a 10% solution). It is contraindicated in IgA-deficient patients with antibodies against IgA and history of hypersensitivity.

WARNING: THROMBOSIS, RENAL DYSFUNCTION AND ACUTE RENAL FAILURE

Please see accompanying full Prescribing Information for additional important information.

- Thrombosis may occur with immune globulin intravenous (IGIV) products, including Octagam 10%. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.
- Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients who receive IGIV products, including Octagam 10%. Patients predisposed to renal dysfunction include those with a degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. Octagam 10% does not contain sucrose.
- For patients at risk of thrombosis, renal dysfunction or acute renal failure, administer Octagam 10% at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

Important Safety Information

Octagam 10% contains maltose, a disaccharide which is derived from corn. Patients known to have corn allergies should avoid using octagam 10%. Hemolysis that is either intravascular or due to enhanced red blood cell sequestration can develop subsequent to octagam 10% treatments. Risk factors for hemolysis include high doses and non-O-blood group. Closely monitor patients for hemolysis and hemolytic anemia.

Adverse Reactions

DM – The most common adverse reactions reported in >5% of study subjects were headache, fever, nausea, vomiting, increased blood pressure, chills, musculoskeletal pain, increased heart rate, dyspnea, and infusion site reaction.

cITP – The most common adverse reactions reported in >5% of study subjects were headache, fever, and increased heart rate.

