הודעה על החמרה (מידע בטיחות) בעלון לרופא
(מעודכן 3102.50)

תאריך 13.5.2013

שם תכשיר באנגלית ומספר הרישום Omr-IgG-am 00 30698 54 127

שם בעל הרישום Omrix Biopharmaceuticals Ltd

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
טקסט חדש	**טקסט נוכחי**	**פרק בעלון**
		Indication
		Contraindications
		Posology, Dosage & Administration
General Adequate hydration prior to the initiation of IVIG infusion is required. Potential complications can often be avoided by ensuring that patients: • Are not sensitive to human immunoglobulin by initial injecting the product slowly. • Are carefully monitored for any symptoms throughout the infusion period. In particular patients naïve to human immunoglobulin, patients switched from an alternative IVIg product or when there has been a long interval since the previous infusion should be monitored during the first infusion and for the first hour after the first infusion, in order to detect potential adverse signs. All other patients should be observed for at least 20 minutes after administration. Certain severe adverse drug reactions may be related to the rate of infusion, therefore recommended infusion rate given under "Dosage and Administration" must be closely followed. **Patients naive to immunoglobulin G (IgG)** Patients naive to immunoglobulin G (IgG) usually experience a higher frequency of events than those well maintained on regular therapy. The recommended infusion rate given under "Dosage and Administration" must be closely followed and patients must be closely monitored and carefully observed for any symptoms throughout the infusion period, and for 1 hour after the first infusion. In case of adverse reactions either the rate of administration must be reduced or the	Adequate hydration prior to the initiation of IVIG infusion is required. Certain severe adverse drug reactions may be related to the rate of infusion Patients naive to immunoglobulin G (IgG) usually experience a higher frequency of events than those well maintained on regular therapy. The recommended infusion rate given under "Dosage and Administration" must be	**Special Warnings and Special Precautions for Use**

infusion stopped until symptoms disappear	closely followed and patients must be closely monitored and carefully observed for any symptoms throughout the infusion period, and for 1 hour after the first infusion. In case of adverse reactions either the rate of administration must be reduced or the infusion stopped until symptoms disappear. For all other infusions, patients should be observed for at least 20 minutes after administration.	
Patients with agammaglobulinemia or extreme hypogammaglobulinemia Patients with agammaglobulinemia or extreme hypogammaglobulinemia who have not received immunoglobulin therapy within the preceding 8 weeks may be at risk of developing inflammatory reactions upon the infusion of human immunoglobulins. These reactions are manifested by a rise in temperature, chills, nausea and vomiting, and appear to be related to the rate of infusion.	Patients with agammaglobulinemia or extreme hypogammaglobulinemia who have not received immunoglobulin therapy within the preceding 8 weeks may be at risk of developing inflammatory reactions upon the infusion of human immunoglobulins. These reactions are manifested by a rise in temperature, chills, nausea and vomiting, and appear to be related to the rate of infusion.	
Acute Renal Failure Cases of acute renal failure have been reported in patients receiving IVIg therapy. In most cases, risk factors have been identified, such as pre-existing renal insufficiency, systemic lupus erythematosis diabetes mellitus, hypovolaemia, overweight, concomitant nephrotoxic medicinal products or age over 65.	In patients with renal failure, diabetes, hypovolemia, obesity, those with systemic lupus erythematosis and renal involvement, receiving concomitant nephrotoxic medications or aged over 65 years,	
Hemolysis Heightened awareness of the potential for hemolysis is recommended in individuals receiving immune globulin products, particularly those who are determined to be at increased risk. Patients at increased risk for hemolysis following treatment with immune globulins include those with non-O blood group types, those who have underlying associated inflammatory conditions, and those receiving high cumulative doses of immune globulins over the course of several days.	Not mentioned	

Patients receiving immune globulin products should be monitored for hemolysis, particularly those at increased risk. Clinical symptoms and signs of hemolysis include fever, chills and dark urine. If these occur, appropriate laboratory testing should be obtained.		
Thrombolytic Events Despite the new step to remove detectable thrombosis-generating agents**,** there is clinical evidence of an association between IVIg administration and thromboembolic events such as myocardial infarction, cerebral vascular accident (including stroke), pulmonary embolism and deep vein thrombosis which is assumed to be related to a relative increase in blood viscosity through the high influx of immunoglobulin in at-risk patients. Care should be used when immune globulin products are given to individuals determined to be at increased risk of thrombosis. Caution should be exercised in prescribing and infusing IVIg in obese patients and in patients with pre-existing risk factors for thrombotic events (such as acquired or hereditary hypercoagulable states, prolonged immobilization, in dwelling vascular catheters, advanced age, estrogen use hypertension, diabetes mellitus and,,, a history of venus or arterial thrombosis, cardiovascular risk factors (including history of atherosclerosis and/or impaired cardiac output) and hyperviscosity (including cryoglobulins, fasting chylomicronemia and/or high triglyceride levels, and monoclonal gammopathies), vascular disease or thrombotic episodes, acquired or inherited thrombophilic disorders, or patients with prolonged periods of immobilisation, severe hypovolemia, or with diseases which increase blood viscosity). Patients at risk for thrombosis should receive immune globulin products at the slowest infusion rate practicable, and these individuals should be monitored for thrombotic complications. Consideration should also be given to measurement of baseline blood viscosity in individuals at risk for hyperviscosity.	Despite the new step to remove detectable thrombosis-generating agents**,** there is clinical evidence of an association between IVIg administration and thromboembolic events such as myocardial infarction, cerebral vascular accident (including stroke), pulmonary embolism and deep vein thrombosis which is assumed to be related to a relative increase in blood viscosity through the high influx of immunoglobulin in at-risk patients. Caution should be exercised in prescribing and infusing IVIg in obese patients and in patients with pre-existing risk factors for thrombotic events (such as advanced age, hypertension, diabetes mellitus and a history of vascular disease or thrombotic episodes, acquired or inherited thrombophilic disorders, or patients with prolonged periods of immobilisation, severe hypovolemia, or with diseases which increase blood viscosity). In patients at risk for thromboembolic adverse reactions, IVIG products should be administered at the minimum rate of infusion and dose practicable	
Hypersensitivity True hypersensitivity reactions are rare. They can occur in patients with anti-IgA		

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<td>antibodies.
IVIg is not indicated in patients with selective IgA deficiency where the IgA deficiency is the only abnormality of concern.
Rarely, human normal immunoglobulin can induce a fall in blood pressure with anaphylactic reaction, even in patients who had tolerated previous treatment with human normal immunoglobulin.

In all patients, IVIg administration requires:
• adequate hydration prior to the initiation of the infusion of IVIg
• monitoring of urine output
• monitoring of serum creatinine levels
• avoidance of concomitant use of loop diuretics.

In case of renal impairment, IVIg discontinuation should be considered.</td>
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<td>Interaction with Other Medicaments and Other Forms of Interaction</td>
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<td>o Guillain Barré Syndrome
0.4 g/kg/day for 3 to 5 days. Experience in children is limited.

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<td>Dosage</td>
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