הודעה על החמרה (מידע בטיחות) בעלון לרופא

תאריך 7.3.2012

שם תכשיר באנגלית Omr-IgG-am_

מספר רישום 127 54 30698 00

שם בעל הרישום: Omrix Biopharmaceuticals Ltd

פרטים על השינוי/ים המבוקש/ים		
טקסט חדש	**טקסט נוכחי**	
Adequate hydration prior to the initiation of IVIG infusion is required **For all other infusions, patients should be observed for at least 20 minutes after administration.** **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.**	Not mentioned Not mentioned There is clinical evidence of an association between IVIg administration and thromboembolic events such as myocardial infarction, stroke, pulmonary embolism and deep vein thromboses which is assumed to be related to a relative increase in blood viscosity through the high influx of immunoglobulin in at-risk patients	**Warnings and Special Precautions**
Omr-IgG-am ™ 5% IV is contra- indicated in individuals who are known to have anaphylactic or severe systemic response to intramuscular or intravenous immunoglobulin preparations **or to any of the excipients.**	Omr-IgG-am ™ 5% IV is contra-indicated in individuals who are known to have anaphylactic or severe systemic response to intramuscular or intravenous immunoglobulin preparations	**Contraindications**
		Adverse events

Live attenuated vaccines Immunoglobulin administration may impair for a period **of at least 6 weeks and up to 3 months** the efficacy of live attenuated virus vaccines such as measles, rubella, mumps and varicella. **After administration of this medicinal product, an interval of 3 months should elapse before vaccination with live attenuated virus vaccines. In the case of measles, this impairment may persist for up to 1 year. Therefore patients receiving measles vaccine should have their antibody status checked.**	Live attenuated vaccines Immunoglobulin administration may impair for a period of at least 3 months the efficacy of live attenuated virus vaccines such as measles, rubella, mumps, and varicella.	
The product information of the blood glucose testing system, including that of the test strips, should be carefully reviewed to determine if the system is appropriate for use with maltose-containing parenteral products. If any uncertainty exists, contact the manufacturer of the testing system to determine if the system is appropriate for use with maltose-containing parenteral products. **The interference of maltose in blood glucose assays may result in falsely elevated glucose readings and, consequently, in the inappropriate administration of insulin, resulting in life threatening hypoglycaemia and death**.	The product information of the blood glucose testing system, including that of the test strips, should be carefully reviewed to determine if the system is appropriate for use with maltose-containing parenteral products. If any uncertainty exists, contact the manufacturer of the testing system to determine if the system is appropriate for use with maltose-containing parenteral products.	**Drug interactions and other forms of interactions**
Effects on ability to drive and use machines **The ability to drive and operate machines may be impaired by some adverse reactions associated with Omr-IgG-am. Patients who experience adverse reactions during treatment should wait for these to resolve before driving or operating machines**	Effects on ability to drive and use machines There is no indication that immunoglobulins may impair the ability to drive and use machines.	

Administration ~~• Omr-IgG-am ™ 5% IV should be infused intravenously at an initial rate of 0.01-0.02 ml/kg/min for 15 minutes.~~ ~~• Infusion rate may increase gradually to a maximum of 0.08 ml/kg/min.~~ ~~• It is recommended not to exceed a rate of 2 ml/min.~~ ~~• Avoid suggested dose escalations.~~ ~~• Infusion should not exceed more than 5 hours.~~ ~~• The daily dose should not exceed 400-500 mg/kg/day~~ **• Omr-IgG-am ™ 5% IV should be infused intravenously at an initial rate of 0.01-0.02 mL/kg/min for 15 minutes.** **• Infusion rate may increase gradually to a maximum of 0.08 mL/kg/min.** **• It is recommended not to exceed a rate of 2 mL/min.**	Administration Omr-IgG-am ™ 5% IV should be infused intravenously at an initial rate of 0.01-0.02 ml/kg/min for 15 minutes, increasing gradually to a maximum of 0.08 ml/kg/min. However it is recommended not to exceed a rate of 3 ml/min.	**Others: Administration**
Overdose may lead to fluid overload and hyperviscosity, particularly in patients at risk, including elderly patients or patients with cardiac or renal impairment	Consequences of overdosage are not known	**Others; Overdose**
Keep out of reach of children	Not mentioned	**Storage conditions**

השינויים המבוקשים מסומנים על רקע צהוב

.....