הודעה על החמרה (מידע בטיחות) בעלון לרופא

תאריך 04/06/12

שם תכשיר באנגלית: PRIVIGEN

מספר רישום 146 46 33254

שם בעל הרישום מדיליין בע"מ

השינויים בעלון מסומנים על רקע צהוב

בעלון לרופא

פרטים על השינוי/ים המבוקש/ים		
פרק בעלון	**טקסט נוכחי**	**טקסט חדש**
Warnings and precautions		Haemolytic anaemia IVIg products can contain blood group antibodies which may act as haemolysins and induce in vivo coating of red blood cells (RBC) with immunoglobulin, causing a positive direct antiglobulin reaction (Coomb's test) and, rarely, haemolysis. Haemolytic anaemia can develop subsequent to IVIg therapy due to enhanced RBC sequestration. Isolated cases of haemolysis-related renal dysfunction/renal failure or disseminated intravascular coagulation have occurred. The following risk factors are associated with the development of haemolysis: high doses, whether given as a single administration or divided over several days; and blood group A, B and AB combined with underlying inflammatory state. Increased vigilance is recommended for patients with blood group A, B or AB receiving high doses for non-PID indications. Haemolysis has rarely been reported in patients given replacement therapy for PID. IVIg recipients should be monitored for clinical signs and symptoms of haemolysis. If signs and/or symptoms of haemolysis develop during or after IVIg infusion, discontinuation of IVIg treatment should be considered by the treating physician (see also section "Undesirable effects"). Aseptic meningitis syndrome (AMS) Aseptic meningitis syndrome has been reported to occur in association with IVIg treatment. Discontinuation of IVIg treatment has resulted in remission of AMS within several days without sequelae. The syndrome usually begins within several hours to 2 days following IVIg treatment. Cerebrospinal fluid studies are frequently positive with pleocytosis up to several thousand cells per mm3, predominantly from the granulocytic series, and elevated protein levels up to several hundred mg/dl. AMS may occur more frequently in association with high-dose (2 g/kg) IVIg treatment.