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

תאריך: 6 באוקטובר 2015

שם תכשיר באנגלית ומספר הרישום Gammaplex 145-40-33225-00

שם בעל הרישום Kamada Ltd

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות

פרק בעלון	טקסט נוכחי	טקסט חדש
Undesirable effects	**MedDRA Standard System Organ Class** / **Undesirable effects** / **Frequency** Metabolism and nutrition / Fluid retention / Common Dehydration, Decreased appetite, iron deficiency / Uncommon General disorders and administration site conditions / Pyrexia, Chills, chest discomfort, fatigue, asthenia, infusion site reaction, pain / Common Investigations / Coombs' direct test positive / Common Haemoglobin decreased, antibody test positive, white blood cell count increased, urinary haemosiderin positive / Uncommon	**MedDRA Standard System Organ Class** / **Undesirable effects** / **Frequency** Metabolism and nutrition / Fluid retention / Common Dehydration, Decreased appetite, iron deficiency / Uncommon General disorders and administration site conditions / Pyrexia / Very common Chills, chest discomfort, fatigue, asthenia, infusion site reaction, pain / Common Investigations / Coombs' direct test positive / Common Haemoglobin decreased, anti-erythrocyte antibody positive, white blood cell count increased, urinary haemosiderin positive / Uncommon
	Paediatric population Of the 50 patients in the clinical study of Gammaplex® in primary immunodeficiency, seven were aged less than 18 years (age range 9 to 17 years). Of the 29 patients in the clinical study of Gammaplex® in chronic immune thrombocytopenia (ITP), three were aged less than 18 years (age range 6 to 17 years). The	**Paediatric population** Of the 50 patients in the clinical study of Gammaplex® in primary immunodeficiency, seven were aged less than 18 years (age range 9 to 17 years). Of the ~~29~~35 patients in the clinical study of Gammaplex® in chronic immune thrombocytopenia (ITP), three were aged less than 18 years (age range 6 to 17 years). The frequency, type and severity of adverse reactions in children are

expected to be the same as in adults.	frequency, type and severity of adverse reactions in children are expected to be the same as in adults.	
תוספת: **Reporting of suspected adverse reactions** Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form (http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.health.gov.il) or by email (adr@MOH.HEALTH.GOV.IL). Additionally, you should also report to Kamada LTD.		
A phase III, multicentre, non-randomized, open-label study in 50 subjects with primary immunodeficiency diseases (PID), where Gammaplex® was infused at a dose of 300 to 800 mg/kg every 21 or 28 days, concluded that Gammaplex® was well tolerated and efficacious and therefore suitable for the management of subjects with PID. There were no serious acute bacterial infections during the 12 months of treatment, and the most commonly reported adverse reactions were headache (18 patients), nausea (6 patients), pyrexia (6 patients) and fatigue (6 patients). A later phase III, open-label, multicentre clinical study investigating the safety and efficacy of Gammaplex® infused at a dose of 1 g/kg/day for two consecutive days in 35 subjects with chronic immune thrombocytopenic purpura (ITP) showed Gammaplex® to be an effective treatment, and hence its efficacy in immunomodulation. The most commonly reported adverse reactions were headache (10 patients), vomiting (6 patients) and pyrexia (5 patients).	A phase III, multicentre, non-randomized, open-label study in 50 subjects with primary immunodeficiency diseases (PID), where Gammaplex® was infused at a dose of 300 to 800 mg/kg every 21 or 28 days, concluded that Gammaplex® was well tolerated and efficacious and therefore suitable for the management of subjects with PID. There were no serious acute bacterial infections during the 12 months of treatment, and the most commonly reported adverse reactions were headache (9 patients), nausea (6 patients), pyrexia (6 patients) and fatigue (6 patients). A later phase III, open-label, multicentre clinical study investigating the safety and efficacy of Gammaplex® infused at a dose of 1 g/kg/day for two consecutive days in 29 subjects with chronic immune thrombocytopenia (ITP) showed Gammaplex® to be an effective treatment, and hence its efficacy in immunomodulation. The most commonly reported adverse reactions were headache (18 patients), vomiting (5 patients) and pyrexia (4 patients).	Pharmacodynamic properties

The product should be brought to room temperature before use. The solution should be clear or slightly opalescent and colourless or pale yellow. Solutions that are cloudy or have deposits should not be used. Any unused product or waste material should be disposed of in accordance with local requirements.	The product should be brought to room temperature before use. Gammaplex® should be clear or slightly opalescent and colourless. Solutions that are cloudy or have deposits should not be used. Any unused product or waste material should be disposed of in accordance with local requirements.	Special precautions for disposal and other handling

מצ"ב העלון, שבו מסומנות ההחמרות המבוקשות על רקע צהוב.
שינויים שאינם בגדר החמרות סומנו (בעלון) **בטקסט מודגש באפור.** יש לסמן רק תוכן מהותי ולא שינויים במיקום הטקסט.

העלון הועבר בדואר אלקטרוני בתאריך: 07-10-2015

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