הודעה על החמרה (מידע בטיחות) בעלון לרופא (מעודכן 05.2013)

תאריך 09/11/2016

שם תכשיר באנגלית ומספר הרישום
Gammaplex מספר רישום 145-40-33225

שם בעל הרישום Kamada Ltd

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות

טקסט חדש

MedDRA Standard System Organ Class	Undesirable effects	Frequency
Nervous system disorders	Headache	Very common
	Dizziness, ~~lethargy~~	Common
	Migraine, hypoaesthesia, paraesthesia, lethargy	Uncommon
Cardiac disorders	Palpitations, tachycardia	Common
	~~Tachycardia~~	~~Uncommon~~
Vascular disorders	Hypertension, hypotension	Common
	Thrombosis, hot flush,	Uncommon
Gastrointestinal disorders	Vomiting, nausea, diarrhoea, abdominal pain,	Common
	Abdominal distension, constipation, stomatitis, ~~gastric acidity~~	Uncommon
General disorders and administration site conditions	Pyrexia	Very common
	Chills, chest discomfort/ pain, fatigue, asthenia, infusion site reaction, infusion site erythema, pain	Common
Investigations	Coombs' direct test positive, anaemia/ haemoglobin decreased	Common
	~~Haemoglobin decreased~~, ~~a~~Anti-erythrocyte antibody positive, white blood cell count increased, urinary haemosiderin positive, gastric pH decreased	Uncommon

Paediatric population
Of the 50 patients in the clinical study of Gammaplex® in primary immunodeficiency

טקסט נוכחי

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פרק בעלון

Adverse events

(GMX01), seven were aged less than 18 years (age range 9 to 17 years). A separate paediatric clinical study of Gammaplex in primary immunodeficiency (GMX04) treated 25 patients aged less than 18 years (age range 3 to 16 years). Of the 35 patients in the clinical study of Gammaplex® in chronic immune thrombocytopenia (ITP) (GMX02), three were aged less than 18 years (age range 6 to 17 years). The frequency, type and severity of adverse reactions in children are similar to those ~~expected to be the same as~~ in adults.	seven were aged less than 18 years (age range 9 to 17 years). Of the 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.	
Paediatric population GMX04 A phase III, multicentre, non-randomized, open-label paediatric study in 25 children and adolescent subjects (aged 3-16 years inclusive) 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 in children with PID. There were two serious acute bacterial infections reported during the 12 months of treatment, and the most commonly reported adverse reactions were headache (8 patients), hypotension (4 patients), pyrexia (3 patients) and tachycardia (3 patients).	**Paediatric population**	**Pharmacodynamic properties**
Pharmacokinetic properties Human normal immunoglobulin is immediately and completely bioavailable in the recipient's circulation after intravenous administration. It is distributed relatively rapidly between plasma and extravascular fluid, and after approximately 3 - 5 days equilibrium is reached between the intra- and extravascular compartments. At steady state Gammaplex has a median ~~Gammaplex® has a~~ half-life in adults of 31.3 days (range 21.1 days to 42.7 days)~~about 21.7 days (mean after single dose) and about 35.5 days (median at steady state)~~. This half-life may vary from patient to patient, in particular in primary immunodeficiency. IgG and IgG-complexes are broken down in cells of the reticuloendothelial system. **Paediatric population** Pharmacokinetic data is available from 25 paediatric patients across the two PID studies: GMX01 (2/50 patients were included in the paediatric PK analysis) and GMX04 (23/25 patients were included in the PK analysis). At steady state Gammaplex was shown to have a median half-life in children of 35.5 days (range 24.2 to 76.2 days). ~~Two children participated in a PK sub-study as part of the study in subjects with PID. Gammaplex® was shown to have a half-life of 33.9 to 69.7 days, confirming variability between patients.~~	**Pharmacokinetic properties** Human normal immunoglobulin is immediately and completely bioavailable in the recipient's circulation after intravenous administration. It is distributed relatively rapidly between plasma and extravascular fluid, and after approximately 3 - 5 days equilibrium is reached between the intra- and extravascular compartments. Gammaplex® has a half-life of about 21.7 days (mean after single dose) and about 35.5 days (median at steady state). This half-life may vary from patient to patient, in particular in primary immunodeficiency. IgG and IgG-complexes are broken down in cells of the reticuloendothelial system. **Paediatric population** Two children participated in a PK sub-study as part of the study in subjects with PID. Gammaplex® was shown to have a half-life of 33.9 to 69.7 days, confirming variability between patients.	**Pharmacokinetic properties**