04/03/2018

רופא/ה, רוקח/ת נכבד/ה,

חברת קמהדע מבקשת להודיע על עידכון מידע כמפורט להלן, עבור התכשיר:

אינטראטקט 50 גרם/ליטר ; Intratect 50 g/l

Solution for Infusion, IV

מרכיבים פעילים בהתאם לרישיון: Human Plasma Protein 50mg/1ml

המאושר להתויה:

Replacement therapy in adults, and children and adolescents (0-18 years) in:

- Primary immunodeficiency syndromes with impaired antibody production.
- Hypogammaglobulinaemia and recurrent bacterial infections in patients with chronic lymphocytic leukaemia, in whom prophylactic antibiotics have failed.
- Hypogammaglobulinaemia and recurrent bacterial infections in plateau phase multiple myeloma patients who have failed to respond to pneumococcal immunisation.
- Hypogammaglobulinaemia in patients after allogeneic haematopoietic stem cell transplantation (HSCT).
- Congenital AIDS with recurrent bacterial infections.

Immunomodulation in adults, and children and adolescents (0-18 years) in:

- Primary immune thrombocytopenia (ITP), in patients at high risk of bleeding or prior to surgery to correct the platelet count.
- Guillain Barré syndrome.
- Kawasaki disease.

מהות השינוי:

1. אושר שינוי שם התכשיר מ- Intratect ל- Intratect 50g/l:

INTRATECT 50 g/l

2. בנוסף, עודכן עלון התכשיר, סעיף 4.8. מפורטים להלן רק תתי-הסעיפים שבהם נעשו העידכונים העיקריים. מידע חדש הודגש בצבע:

4.8 Undesirable effects

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Tabulated list of adverse reactions

Suspected Adverse Drug Reactions reported in completed clinical trials:

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Three clinical studies have been performed with Intratect 50 g/l: two in patients with primary immunodeficiencies (PID) and one in patients with immune thrombocytopenic purpura (ITP). In the two PID studies overall 68 patients were treated with Intratect 50 g/l and evaluated for safety. Treatment period was 6 and 12 months respectively. The ITP study was performed in 24 patients.

These 92 patients received a total of 830 infusions of Intratect 50 g/l, whereby a total of 51 adverse drug reactions (ADRs) were recorded.

With Intratect 100 g/l one clinical study has been performed in patients with PID. 30 patients were treated with Intratect 100 g/l over 3 to 6 months and evaluated for safety. These 30 patients received a total of 165 infusions of Intratect 100 g/l, whereof a total of 19 infusions (11.5%) were associated with adverse drug reactions (ADRs).

The majority of these ADRs was mild to moderate and self-limiting. No serious ADRs were observed during the studies.

The table presented below is according to the MedDRA system organ classification (SOC and Preferred Term Level).

Frequencies have been evaluated according to the following convention: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data).

Frequency of Adverse Drug Reactions (ADRs) in clinical studies with Intratect 50 g/l, **indications PID and ITP** *(Frequencies are calculated per infusions administered (n=830) and patients treated (n=92) respectively.)*

MedDRA System Organ Class (SOC)	**Adverse reaction (MedDRA preferred term (PT))**	***Frequency*** *based on infusions administered (n=830)*	***Frequency*** *based on patients treated (n=92)*
Blood and lymphatic system disorders	Haemolysis (mild)	Uncommon	Common
Nervous system disorders	Headache	Common	Very Common
	Dysgeusia	Uncommon	Common
Vascular disorders	Hypertension, thrombophlebitis superficial	Uncommon	Common
Gastrointestinal disorders	Nausea, vomiting, gastrointestinal pain	Uncommon	Common

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Skin and subcutaneous tissue disorders	Papular rash	Uncommon	Common
General disorders and administration site conditions	Pyrexia	Common	Very common
	Chills, feeling hot	Uncommon	Common
Investigations	Body temperature increased, Coombs test (indirect and direct) positive	Uncommon	Common

Frequency of Adverse Drug Reactions (ADRs) in a clinical study with Intratect 100 g/l, indication PID *(Frequencies are calculated per infusions administered (n=165 and patients treated (n=30) respectively)*

MedDRA System Organ Class (SOC)	**Adverse reaction (MedDRA preferred term (PT))**	**Frequency** *based on infusions administered (n=165)*	**Frequency** *based on patients treated (n=30)*
Immune system disorders	Infusion related reaction	Common	Common
	Hypersensitivity	Uncommon	Common
Nervous system disorders	Headache	Common	Common
	Sensory disturbance	Uncommon	Common
Cardiac Disorders	Palpitations	Common	Common
Vascular disorders	Hyperaemia, hypertension	Uncommon	Common
Gastrointestinal disorders	Diarrhoea, abdominal pain	Uncommon	Common
Skin and subcutaneous tissue disorders	Pain of skin, rash	Uncommon	Common
Musculoskeletal and connective tissue disorders	Arthralgia, back pain, bone pain	Common	Common
	Myalgia	Uncommon	Common
General disorders and administration site conditions	Discomfort	Common	Very Common
	Fatigue, chills, hypothermia	Uncommon	Uncommon

Details of further spontaneously reported adverse reactions:

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Frequency: not known (cannot be estimated from the available data)

Cardiac disorders: Angina pectoris

General disorders and administrations site conditions: Rigors

Immune system disorders: Anaphylactic shock, allergic reaction

Investigations: Blood pressure decreased

Musculoskeletal and connective tissue disorders: Back pain

Respiratory, thoracic and mediastinal disorders: Dyspnoe NOS

Vascular disorders: Shock

Blood and lymphatic system disorders: leukopenia

Description of selected adverse reactions

The reported adverse reactions for Intratect are in the expected profile for human normal immunoglobulins.

העלון לרופא המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות: https://www.old.health.gov.il/units/pharmacy/trufot/index.asp, וניתן לקבלו מודפס ע"י פניה לבעל הרישום, חברת קמהדע בע"מ (טל' 08-9406472).

בברכה,

פנינה נודל,

רוקחת ממונה