ינואר 2021

רופא/ה, רוקח/ת נכבד/ה,

הנדון: Kiovig 100mg/mL – עדכון עלון לרופא

חברת טקדה ישראל בע"מ מבקשת להודיעך על עדכון בעלון לרופא של התכשיר שבנדון

התכשיר רשום בישראל להתוויה הבאה:

IVIg can be used in all age ranges, unless otherwise specified below.
Replacement therapy 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 whohave failed to respond to pneumococcal immunisation.
Children and adolescents (age 0-18) with congenital AIDS and recurrent bacterial infections.
Hypogammaglobulinaemia in patients after allogeneic haematopoietic stem cell transplantation (HSCT).
Immunomodulation
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.

מרכיב פעיל: Immunoglobulin Normal Human 100mg/mL

פרטי העדכון העיקריים הינם:

(טקסט שהושמט מסומן ב~~אדום~~, טקסט שנוסף מסומן בטקסט בחול , טקסט המהווה החמרה מודגש בצהוב)

4.3 Contraindications

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Patients with selective IgA deficiency who developed antibodies to IgA, as administering an IgA containing product can result in anaphylaxis.

4.4 Special warnings and precautions for use

Infusion reaction

Certain **severe** adverse reactions **(e.g. headache, flushing, chills, myalgia, wheezing, tachycardia, lower back pain, nausea, and hypotension)** may be related to the rate of infusion.

Certain adverse reactions may occur more frequently

- in case of high rate of infusion
- in patients who receive human normal immunoglobulin for the first time or, in rare cases, when the human normal immunoglobulin product is switched or when there has been a long interval since the previous infusion
- **in patients with an untreated infection or underlying chronic inflammation.**

Precautions for use

Potential complications can often be avoided by ensuring that patients:

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– are not sensitive to human normal immunoglobulin by initially injecting the product slowly (**0.5**~~0.01~~ ml/kg BW/~~min~~hr);
– are carefully monitored for any symptoms throughout the infusion period. In particular, patients naive to human normal immunoglobulin, patients switched from an alternative IVIg product or when there has been a long interval since the previous infusion should be monitored **at the hospital** during the first infusion and for the first hour after the first infusion, in order to detect potential adverse signs. All other patients should be observed for at least 20 minutes after administration.

Hypersensitivity

~~True h~~**H**ypersensitivity reactions are rare.

Anaphylaxis can develop in patients

- **with undetectable IgA who have anti-IgA antibodies**
- **who had tolerated previous treatment with human normal immunoglobulin**

~~They can occur in patients with anti-IgA antibodies. IVIg is not indicated in patients with selective IgA deficiency where the IgA deficiency is the only abnormality of concern.~~

~~Rarely, human normal immunoglobulin can induce a fall in blood pressure with anaphylactic reaction, even in patients who had tolerated previous treatment with human normal immunoglobulin.~~

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Acute renal failure

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Renal parameters should be assessed prior to infusion of IVIg, particularly in patients judged to have a potential increased risk for developing acute renal failure, and again at appropriate intervals. In patients at risk for acute renal failure, IVIg products should be administered at the minimum rate of infusion and dose practicable. In case of renal impairment, IVIg discontinuation should be considered.

Transfusion Related Acute Lung Injury (TRALI)

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TRALI is characterised by severe hypoxia, dyspnoea, tachypnoea, cyanosis, fever and hypotension. Symptoms of TRALI typically develop during or within 6 hours of a transfusion, often within 1-2 hours. Therefore, IVIg recipients must be monitored for and IVIg infusion must be immediately stopped in case of pulmonary adverse reactions. TRALI is a potentially lifethreatening condition requiring immediate intensive-care-unit management.

Aseptic meningitis syndrome (AMS)

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Patients exhibiting such signs and symptoms should receive a thorough neurological examination, including CSF studies, to rule out other causes of meningitis.

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Neutropenia/Leukopenia

A transient decrease in neutrophil count and/or episodes of neutropenia, sometimes severe, have been reported after treatment with IVIgs. This typically occurs within hours or days after IVIg administration and resolves spontaneously within 7 to 14 days.

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Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

~~It is strongly recommended that every time that KIOVIG is administered to a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product.~~

4.5 Interactions with other medicinal products and other forms of interactions

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Loop diuretics

Avoidance of concomitant use of loop diuretics.

4.6 Fertility, pregnancy and lactation

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Breast-feeding

Immunoglobulins are excreted into the milk and may contribute to protecting the neonate from pathogens which have a mucosal portal of entry. **No negative effects on the breastfed newborn/infants are anticipated.**

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4.8 Undesirable effects

Summary of the safety profile

Adverse reactions such as chills, headache, **dizziness,** fever, vomiting, allergic reactions, nausea, arthralgia, low blood pressure and moderate low back pain may occur occasionally.

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Cases of reversible aseptic meningitis and rare cases of transient cutaneous reactions **(including cutaneous lupus erythematosus - frequency unknown)** have been observed with human normal immunoglobulin.

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Cases of Transfusion Related Acute Lung Injury (TRALI).

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העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות.

כמו כן, ניתן לקבל העתק מודפס של העלון באמצעות פנייה לבעל הרישום:

טקדה ישראל בע"מ, רח' אפעל 25 , פתח-תקווה, טל': 03-3733140

בברכה,

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