יולי 2019

רוקח/ת נכבד/ה
רופא/ה נכבדה,

הנדון : עדכון עלון לרופא לתכשיר
Octagam , solution for I.V. infusion
אוקטאגם, תמיסה לאינפוזיה למתן תוך ורידי

חברת דובר מכשור רפואי ומדעי בע"מ מבקשת להודיע על עדכונים בעלון לרופא לתכשיר Octagam.

החומר הפעיל בתכשיר:

Human normal immunoglobulin 50 mg/ml

ההתוויה המאושרת לתכשיר:

Replacement therapy in:

Primary immunodeficiency syndromes such as:

- congenital agammaglobulinaemia and hypogammaglobulinaemia
- common variable immunodeficiency
- severe combined immunodeficiency
- Wiskott Aldrich syndrome
- Myeloma or chronic lymphatic leukaemia with severe secondary Hypogammaglobulinaemia and recurrent infections
- Children with congenital AIDS and recurrent bacterial infections

Immunomodulatory effect:

- Idiopathic thrombocytopenic purpura (ITP) in children or adults at high risk of bleeding or prior to surgery to correct the platelet count.
- Guillain Barré syndrome
- Kawasaki disease

Allogeneic bone marrow transplantation

העלון הישראלי עודכן באפריל 2019 על פי עלון המאושר בבריטניה.
בהודעה זו מצוינים סעיפים בהם נעשה עדכון המהווה החמרה - מודגש בצהוב.
בעלונים קיימים עדכונים נוספים שאינם מהווים החמרה.
למידע מלא על התרופה יש לעיין בעלון לרופא כפי שאושר על ידי משרד הבריאות.
העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות:

https://data.health.gov.il/drugs/index.html#/byDrug

ניתן לקבל את העלון מודפס ע"י פנייה לבעל הרישום: דובר מכשור רפואי ומדעי בע"מ, המעלות 11, הרצליה. טלפון : 09-9514545

בכבוד רב, רבקה סלונים
רוקחת ממונה

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דובר מיכשור רפואי ומדעי בע"מ
המעלות 11, הרצליה 46583
טל: 09-9514545 פקס: 09-9580151

העדכונים העיקריים בעלון לרופא נעשו בסעיפים הבאים:

2. Qualitative and quantitative composition

[…]

Produced from plasma of human donors.

4.4 Special warnings and precautions for use

[…]

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.

Potential complications can often be avoided by ensuring that patients:

- are not sensitive to human normal immunoglobulin by initially injecting the product slowly (1 ml/kg/hour);
- 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 to OCTAGAM or when there has been a long interval since the previous infusion should be monitored 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.

[…]

In all patients, IVIg administration requires:

[…]

- avoidance of concomitant use of loop diuretics.

This medicinal product contains not more than 0.015 mmol (or 0.35 mg) sodium per ml. To be taken into consideration by patients on a controlled sodium diet.

Hypersensitivity

[…]

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.

Thromboembolism

[…]

In patients at risk for thromboembolic adverse reactions, IVIg products should be administered at the minimum rate of infusion and dose practicable.

[…]

Aseptic meningitis syndrome (AMS)

[...]

AMS may occur more frequently in association with high-dose (2 g/kg) IVIg treatment.

Haemolytic anaemia

[…]

The development of haemolysis is associated with the following risk factors: high IVIg doses administered as a single dose or in divided doses over several days; blood groups other than group O; underlying inflammatory disease. Haemolysis has only rarely been observed in patients receiving substitution therapy for PID.

[…]

Transmissible agents

Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses.

[…]

The measures taken are considered effective for enveloped viruses such as HIV, HBV and HCV.

The measures taken may be of limited value against non-enveloped viruses such as HAV and parvovirus B19.

There is a reassuring clinical experience regarding the lack of hepatitis A or parvovirus B19 transmission with immunoglobulins and it is also assumed that the antibody content makes an important contribution to the viral safety.

It is strongly recommended that every time that OCTAGAM 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.

Transfusion-related acute lung injury (TRALI)

There have been reports of non-cardiogenic pulmonary oedema [Transfusion-Related Acute Lung Injury (TRALI)] in patients treated with IVIG, therefore, this side effect cannot be totally excluded for Octagam even though no case has been observed so far for Octagam. […]

(Falsely) raised erythrocyte sedimentation rate

In patients who are receiving IVIG as a therapy, the erythrocyte sedimentation rate (ESR) may falsely be increased (noninflammatory rise).

Circulatory (volume) overload

Circulatory (volume) overload can occur when the volume of the infused IVIG (or any other blood or plasma-derived product) and other coincidental infusions cause acute hypervolaemia and acute pulmonary oedema.

Local injection site reactions:
Local reactions at the injection site have been identified which might include extravasation, infusion site erythema, infusion site pruritus, and similar symptoms.

[…]

4.5 Interaction with other medicinal products and other forms of interaction

[…]

Blood Glucose Testing

Some types of blood glucose testing systems […] falsely interpret the maltose (100 mg/ml) contained in OCTAGAM as glucose. This may result in falsely elevated glucose readings during an infusion and for a period of about 15 hours after the end of the infusion […] when administering OCTAGAM or other parenteral maltose- containing products, the measurement of blood glucose must be done with a glucose-specific method.
[…]

4.6 Fertility, pregnancy and lactation

Pregnancy
[…] IVIg products have been shown to cross the placenta, increasingly during the third trimester.
[…]

4.7 Effects on ability to drive and use machines

The ability to drive and operate machines may be impaired by some adverse reactions associated with OCTAGAM. Patients who experience adverse reactions during treatment should wait for these to resolve before driving or operating machines.

4.8 Undesirable effects

הסעיף כולו נערך מחדש.

[…] Cases of reversible aseptic meningitis and rare cases of transient cutaneous reactions have been observed with human normal immunoglobulin. Reversible haemolytic reactions have been observed in patients, especially those with blood groups A, B, and AB. Rarely, haemolytic anaemia requiring transfusion may develop after high dose IVIg treatment (see also Section 4.4).

Increase in serum creatinine level and/or acute renal failure have been observed.

Very rarely: Thromboembolic reactions such as myocardial infarction, stroke, pulmonary embolism, deep vein thromboses.

When medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens. For safety with respect to transmissible agents, see Section 4.4.

Tabulated list of adverse reactions

[…]

MedDRA system organ classification (SOC)	**Adverse Reaction (Preferred Term Level)**	**Frequency**
Metabolic and nutritional disorders	fluid overload (pseudo)hyponatraemia	very rare very rare
Psychiatric disorders	confusional state agitation anxiety nervousness	very rare very rare very rare very rare
Nervous system disorders	cerebrovascular accident (see 4.4); meningitis aseptic; loss of consciousness; speech disoder; migraine; headache dizziness; hypoaesthesia; paraesthesia photophobia; tremor	very rare very rare very rare very rare very rare common very rare very rare very rare very rare very rare
Eye disorders	visual impairment	very rare
Cardiac disorders	myocardial infarction (see 4.4); angina pectoris; bradycardia; tachycardia; palpitations; cyanosis	very rare very rare very rare very rare very rare very rare
Vascular disorders	thrombosis (see 4.4); circulatory collapse; peripheral circulatory failure; phlebitis; hypotension; hypertension pallor	very rare very rare very rare very rare very rare very rare very rare
Respiratory, thoracic and mediastinal disorders	respiratory failure; pulmonary embolism (see 4.4); pulmonary oedema; bronchospasm; hypoxia; dyspnoea; cough;	very rare very rare very rare very rare very rare very rare very rare

Skin and subcutaneous tissue disorders	skin exfoliation; urticaria; rash; rash erythematous; dermatitis; eczema; pruritus; alopecia erythema;	very rare very rare very rare very rare very rare uncommon very rare very rare very rare
Musculoskeletal and connective tissue disorders	arthralgia; myalgia pain in extremity back pain; neck pain; muscle spasms; muscular weakness; musculoskeletal stiffness	very rare very rare very rare uncommon very rare very rare very rare very rare
Renal and urinary disorders	renal failure acute (see 4.4) renal pain	very rare very rare
General disorders and administration site conditions	chest pain; chest discomfort; oedema; influenza like illness fever; chills; hot flush; flushing; feeling cold; feeling hot; hyperhidrosis; asthenia; lethargy; burning sensation; injection site reaction; fatigue; malaise;	uncommon very rare very rare very rare common uncommon very rare very rare very rare very rare very rare very rare very rare very rare common common very rare
[…]		

Description of selected adverse reactions

[…]

Paediatric population

In clinical studies with OCTAGAM most adverse reactions observed in children were graded as mild and many of them responded to simple measurements such as reduction of the infusion rate or temporary discontinuation of the infusion. With respect to the type of adverse reaction, all were recognised for IVIG preparations. The most frequent adverse reaction observed in the paediatric population was headache.

[…]

4.9 Overdose

Overdose may lead to fluid overload and hyperviscosity, particularly in patients at risk, including elderly patients or patients with cardiac or renal impairment.

[…]

6.6 Special precautions for disposal and other handling

The product should be brought to room or body temperature before use.

Do not use solutions that are cloudy or have deposits.

[…]