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SUMMARY OF THE PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

OCTAGAM

50 mg/ml solution for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Human normal immunoglobulin (IVIg)

One ml contains :
Human normal immunoglobulin* 50 mg
* corresponding to the total protein content of which at least 95% is human Immunoglobulin G

Maximum IgA content: 200 micrograms/ml

Each bottle of 50 ml contains 2.5g of human normal immunoglobulin.
Each bottle of 100 ml contains 5g of human normal immunoglobulin.
Each bottle of 200 ml contains 10g of human normal immunoglobulin.

Produced from plasma of human donors.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology

The dose and dosage regimen is dependant on the indication.
In replacement therapy the dosage may need to be individualised for each patient dependant on the pharmacokinetic and clinical response.
The following dosage regimens are given as a guideline.

Replacement therapy in primary immunodeficiency syndromes:

- The dosage regimen should achieve a trough level of IgG (measured before the next infusion) of at least 4.0 - 6.0 g/l. Three to six months are required after the initiation of therapy for equilibration to occur. The recommended starting dose is 0.4 - 0.8 g/kg followed by at least 0.2 g/kg every three weeks.
- The dose required to achieve a trough level of 6.0 g/l is of the order of 0.2 - 0.8 g/kg/month.
- The dosage interval, when steady state has been reached varies from 2 to 4 weeks.
- Trough levels should be measured in order to adjust the dose and dosage interval.

Replacement therapy in myeloma or chronic lymphatic leukaemia with severe secondary hypogammaglobulinaemia and recurrent infections; replacement therapy in children with AIDS and recurrent infections:

- The recommended dose is 0.2-0.4 g/kg every three to four weeks.

Idiopathic Thrombocytopenic Purpura:

- For the treatment of an acute episode, 0.8-1.0 g/kg on day one, which may be repeated once within 3 days , or 0.4 g/kg daily for two to five days.
- The treatment can be repeated if relapse occurs.

Guillain Barré Syndrome:

- 0.4 g/kg/day for 3 to 7 days. Experience in children is limited.

Kawasaki Disease:

- 1.6-2.0 g/kg should be administered in divided doses over two to five days or 2.0 g/kg as a single dose. Patients should receive concomitant treatment with acetylsalicylic acid.

Allogeneic Bone Marrow Transplantation:

- Human normal immunoglobulin treatment can be used as part of the conditioning regimen and after the transplant. For the treatment of infections and prophylaxis of graft versus host disease, dosage is individually tailored.
- The starting dose is normally 0.5 g/kg/week, starting seven days before transplantation and for up to 3 months after transplantation.
- In the case of persistent lack of antibody production, dosage of 0.5 g/kg/month is recommended until antibody level returns to normal.

The dosage recommendations are summarised in the following table:

Indication	Dose	Frequency of injection
Replacement therapy in primary immunodeficiency	- Starting dose: 0.4 - 0.8 g/kg - Thereafter: 0.2 - 0.8 g/kg	every 2 - 4 weeks to obtain IgG trough level of at least 4-6 g/l
Replacement therapy in secondary immunodeficiency	0.2 - 0.4 g/kg	every 3 - 4 weeks to obtain IgG trough level of at least 4-6 g/l
Children with AIDS	0.2 – 0.4 g/kg	every 3 - 4 weeks
Immunomodulation:		
Idiopathic Thrombocytopenic Purpura	0.8 – 1.0 g/kg or 0.4 g/kg/day	on day 1, possibly repeated once within 3 days for 2-5 days
Guillain Barré syndrome	0.4 g/kg/day	for 3-7 days
Kawasaki syndrome	1.6 – 2.0 g/kg or 2.0 g/kg	in several doses for 2 - 5 days in association with acetylsalicylic acid in one dose in association with acetylsalicylic acid
Allogeneic bone marrow transplantation:		
- treatment of infections and prophylaxis of graft versus host disease	0.5 g/kg	every week from day -7 up to 3 months after transplantation
- Persistent lack of antibody production	0.5 g/kg	every month until IgG levels return to normal

Method of administration

Human normal immunoglobulin should be infused intravenously at an initial rate of 1 ml/kg/hour for 30 minutes, If well tolerated, the rate of administration may gradually be increased to a maximum of 5 ml/kg/hour.

Filtration of OCTAGAM is not required.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients of OCTAGAM listed in Section 6.1 (see also Section 4.4).
Hypersensitivity to human immunoglobulins, especially in patients with antibodies against IgA.

4.4 Special warnings and precautions for use

This medicinal product contains 100 mg of maltose per ml as an excipient. The interference of maltose in blood glucose assays may result in falsely elevated glucose readings and, consequently, in the inappropriate administration of insulin, resulting in life threatening hypoglycaemia and death. Also, cases of true hypoglycaemia may go untreated if the hypoglycaemic state is masked by falsely elevated glucose readings (see Section 4.5). For acute renal failure see below.

OCTAGAM contains maltose, a disaccharide sugar, which is derived from corn. Anaphylactoid / anaphylactic reactions have been reported in association with infusion of other maltose / corn starch related products. Patients known to have corn allergies should either avoid using OCTAGAM or be closely observed for signs and symptoms of acute hypersensitivity reactions.

Certain severe adverse drug reactions may be related to the rate of infusion. The recommended infusion rate given under Section 4.2 must be closely followed. Patients must be closely monitored and carefully observed for any symptoms throughout the infusion period.

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 case of adverse reaction, either the rate of administration must be reduced or the infusion stopped. The treatment required depends on the nature and severity of the adverse reaction.

In case of shock, standard medical treatment for shock should be implemented.

In all patients, IVIg administration requires:

- adequate hydration prior to the initiation of the infusion of IVIg
- monitoring of urine output
- monitoring of serum creatinine levels
- 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

True hypersensitivity reactions are rare. 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.

Thromboembolism

There is clinical evidence of an association between IVIg administration and thromboembolic events such as myocardial infarction, cerebral vascular accident (including stroke), pulmonary embolism and deep vein thromboses which is assumed to be related to a relative increase in blood viscosity through the high influx of immunoglobulin in at-risk patients. Caution should be exercised in prescribing and infusing IVIg in obese patients and in patients with pre-existing risk factors for thrombotic events (such as advanced age, hypertension, diabetes mellitus and a history of vascular disease or thrombotic episodes, patients with acquired or inherited thrombophilic disorders, patients with prolonged periods of immobilisation, severely hypovolemic patients, patients with diseases which increase blood viscosity).

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

Acute renal failure

Cases of acute renal failure have been reported in patients receiving IVIg therapy. In most cases, risk factors have been identified, such as pre-existing renal insufficiency, diabetes mellitus, hypovolemia, overweight, concomitant nephrotoxic medicinal products or age over 65.

In case of renal impairment, IVIg discontinuation should be considered. While these reports of renal dysfunction and acute renal failure have been associated with the use of many of the licensed IVIg products containing various excipients such as sucrose, glucose and maltose, those containing sucrose as a stabiliser accounted for a disproportionate share of the total number. In patients at risk, the use of IVIg products that do not contain these excipients may be considered. OCTAGAM contains maltose (see excipients above).

In patient at risk for acute renal failure, IVIg products should be administered at the minimum rate of infusion and dose practicable.

Aseptic meningitis syndrome (AMS)
Aseptic meningitis syndrome has been reported to occur in association with IVIg treatment. Discontinuation of IVIg treatment has resulted in remission of AMS within several days without sequelae. The syndrome usually begins within several hours to 2 days following IVIg treatment. Cerebrospinal fluid studies are frequently positive with pleocytosis up to several thousand cells per mm^3, predominantly from the granulocytic series, and elevated protein levels up to several hundred mg/dl.
AMS may occur more frequently in association with high-dose (2 g/kg) IVIg treatment.

Haemolytic anaemia
IVIg products can contain blood group antibodies which may act as haemolysins and induce *in vivo* coating of red blood cells with immunoglobulin, causing a positive direct antiglobulin reaction (Coombs' test) and, rarely, haemolysis. Haemolytic anaemia can develop subsequent to IVIg therapy due to enhanced red blood cells (RBC) sequestration. 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. IVIg recipients should be monitored for clinical signs and symptoms of haemolysis. (See section 4.8.)

Interference with serological testing
After injection of immunoglobulin the transitory rise of the various passively transferred antibodies in the patient's blood may result in misleading positive results in serological testing.
Passive transmission of antibodies to erythrocyte antigens, e.g. A, B, D may interfere with some serological tests for red cell antibodies for example the direct antiglobulin test (DAT, direct Coombs' test).

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. Despite this, 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.

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. TRALI is characterised by severe respiratory distress, pulmonary oedema, hypoxaemia, normal left ventricular function, and fever and typically occurs within 1-6 hours after transfusion.

(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.

Paediatric population
There are no specific or additional warnings or precautions applicable for the paediatric population.

4.5 Interaction with other medicinal products and other forms of interaction

The infusion line may be flushed before and after administration of OCTAGAM with either normal saline or 5% dextrose in water.

Live attenuated virus vaccines

Immunoglobulin administration may impair for a period of at least 6 weeks and up to 3 months the efficacy of live attenuated virus vaccines such as measles, rubella, mumps and varicella. After administration of this product, an interval of 3 months should elapse before vaccination with live attenuated virus vaccines. In the case of measles, this impairment may persist for up to 1 year. Therefore patients receiving measles vaccine should have their antibody status checked.

Blood Glucose Testing

Some types of blood glucose testing systems (for example, those based on the glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase methods) 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 and, consequently, in the inappropriate administration of insulin, resulting in life-threatening hypoglycemia. Also, cases of true hypoglycemia may go untreated if the hypoglycemic state is masked by falsely elevated glucose readings. Accordingly, when administering OCTAGAM or other parenteral maltose- containing products, the measurement of blood glucose must be done with a glucose-specific method.

The product information of the blood glucose testing system, including that of the test strips, should be carefully reviewed to determine if the system is appropriate for use with maltose-containing parenteral products. If any uncertainty exists, contact the manufacturer of the testing system to determine if the system is appropriate for use with maltose-containing parenteral products.

Paediatric population

There were no specific or additional interactions observed for the paediatric population.

4.6 Fertility, pregnancy and lactation

Pregnancy

The safety of this medicinal product for use in human pregnancy has not been established in controlled clinical trials and therefore should only be given with caution to pregnant woman and breast-feeding mothers. IVIg products have been shown to cross the placenta, increasingly during the third trimester. Clinical experience with immunoglobulins suggests that no harmful effects on the course of pregnancy, or on the foetus and the neonate are to be expected.

Breast-feeding

Immunoglobulins are excreted into the milk and may contribute to protecting the neonate from pathogens which have a mucosal portal of entry.

Fertility

Clinical experience with immunoglobulins suggests that no harmful effects on fertility are to be expected.

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

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 occur occasionally. Reactions to intravenous immunoglobulins tend to be related to the dose and the rate of infusion (see section 4.4).

Rarely human normal immunoglobulins may cause a sudden fall in blood pressure and, in isolated cases, anaphylactic shock, even when the patient has shown no hypersensitivity to previous administration.

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

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).

The frequencies given in the following table are derived from clinical studies that were conducted with Octagam (Frequency "common" and "uncommon") and from postmarketing experience with Octagam (Frequency "very rare"). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

MedDRA system organ classification (SOC)	**Adverse Reaction (Preferred Term Level)**	**Frequency**
Blood and lymphatic system disorders	haemolytic anaemia, leukopenia;	very rare very rare
Immune system disorders (see section 4.4)	anaphylactic shock; hypersensitivity anaphylactic reaction; anaphylactoid reaction; angioedema; face oedema	very rare common very rare very rare very rare very rare
Metabolic and nutritional disorders	fluid overload (pseudo)hyponatraemia	very rare very rare
Psychiatric disorders	confusional state agitation anxiety	very rare very rare very rare

	nervousness	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
Gastrointestinal disorders	vomiting; diarrhoea; abdominal pain; nausea	very rare very rare very rare common
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;	uncommon very rare very rare very rare common uncommon

	hot flush; flushing; feeling cold; feeling hot; hyperhidrosis; asthenia; lethargy; burning sensation; injection site reaction; fatigue; malaise;	very rare very rare very rare very rare very rare very rare very rare very rare common common very rare
Investigations	hepatic enzyme increased; blood glucose false positive (see 4.4)	very rare very rare

Description of selected adverse reactions

For description of selected adverse events, see Section 4.4

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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
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.gov.il

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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: immune sera and immunoglobulins: immunoglobulins, normal human, for intravascular administration
ATC code: J06B A02

Human normal immunoglobulin contains mainly immunoglobulin G (IgG) with a broad spectrum of antibodies against infectious agents.

Human normal immunoglobulin contains the IgG antibodies present in the normal population.
It is prepared from pooled material from not fewer than 1000 donations. It has a distribution of immunoglobulin G-subclasses closely proportional to that in native human plasma. Adequate doses of this medicinal product may restore abnormally low immunoglobulin G level to the normal range.
The mechanism of action in indications other than replacement therapy is not fully elucidated, but includes immunomodulatory effects.

Paediatric population

A prospective open-label phase III study was performed with OCTAGAM in 17 children/adolescent patients (median age 14.0 years, range 10.5 to 16.8) suffering from primary immunodeficiency disorders. Previously treated patients received 0.2 g/kg every 3 weeks for the 6 months study period. Naive patients received 0.4 g/kg every 3 weeks for the first 3 months, followed by 0.2 g/kg for the rest of the study period. Dosages had to be adjusted to maintain an IgG trough level of at least 4 g/L.

- No. of days out of school: 11.2 days/patient/year
- No. of days with fever: 4.1 days/patient/year
- No. of days on antibiotics: 19.3 days/patient/year
- No. of days with infections: 29.1 days/patient/year.

The severity of infections was assessed as mild. No severe infections leading to hospitalisation were observed.

5.2 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, after approximately 3-5 days an equilibrium is reached between the intra- and extravascular compartments.
Human normal immunoglobulin has a half-life of about 40 days. 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

A prospective open-label phase III study was performed with OCTAGAM in 17 children/adolescent patients (median age 14.0 years, range 10.5 to 16.8) suffering from primary immunodeficiency disorders. Patients were treated for a period of 6 months.

During the treatment period, the average C_{max} in steady state was 11.1 ± 1.9 g/L; the average trough level was 6.2 ± 1.8 g/L. The mean terminal half-life of total IgG was 35.9 ± 10.8 days with a median of 34 days. The mean volume of distribution for the total IgG was 3.7 ± 1.4 L and the total body clearance was 0.07 ± 0.02 L/day.

5.3 Preclinical safety data

Immunoglobulins are normal constituents of the human body. Studies of repeated dose toxicity, genotoxicity, and toxicity to reproduction in animals are impracticable due to induction of and interference by developing antibodies to heterologous proteins.Since clinical experience provides no evidence for carcinogenic or mutagenic potential of immunoglobulins, no experimental studies in heterogolous species were performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maltose	100 mg/ml
Octoxynol	$\leq$ 5 µg/ml
TNBP [Tri n-butyl phosphate]	$\leq$1 µg/ml
Water for injections	ad 1ml

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

The product should be stored and transported at +2°C to +25°C.
Do not freeze.
Keep container in the outer carton in order to protect from light.
Do not use after expiry date.

6.5 Nature and contents of container

Package size	*Contents*	*Container*
OCTAGAM 1 g	20 ml	30 ml infusion bottle
OCTAGAM 2.5 g	50 ml	70 ml infusion bottle
OCTAGAM 5 g	100 ml	100 ml infusion bottle
OCTAGAM 10 g	200 ml	250 ml infusion bottle

Not all pack sizes may be marketed.

The primary container is made of Ph. Eur. type II glass closed with bromobutyl rubber stopper.

Components used in the packaging of OCTAGAM are latex-free.

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.

Due to the possibility of bacterial contamination, any remaining contents must be discarded.

Any unused product or waste material should be disposed of in accordance with local requirements.

7 REGISTRATION HOLDER

Dover medical & Scientific Equipment Ltd.,
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Herzliya 46583, Israel

8 REGISTRATION NUMBER

143 22 31778 00

9 MANUFACTURER

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