PACKAGE LEAFLET: INFORMATION FOR THE USER

Octagam 50 mg/ml, solution for infusion

Human Normal Immunoglobulin (IVIg)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1 What Octagam 50 mg/ml is and what it is used for

What Octagam 50 mg/ml is:

Octagam 50 mg/ml is a human normal immunoglobulin (IgG) solution (i.e. solution of human antibodies) for intravenous administration (i.e. infusion into a vein). Immunoglobulins are normal constituents of the human body and support the immune defence of your body. Octagam 50 mg/ml contains all IgG activities which are present in the normal population. Adequate doses of this medicinal product may restore abnormally low IgG levels to the normal range.

Octagam 50 mg/ml has a broad spectrum of antibodies against various infectious agents.

What Octagam 50 mg/ml is used for:

Octagam 50 mg/ml is used

- as replacement therapy in patients who do not have sufficient amounts of own antibodies.
- in certain inflammatory diseases.
- to prevent or treat infections after a bone marrow transplantation.

Octagam 50 mg/ml is used as replacement therapy. There are 3 groups of replacement therapy:

- Patients with inborn deficiency of antibodies (primary immunodeficiency syndromes: congenital agammaglobulinaemia and hypogammaglobulinaemia, common variable immunodeficiency, severe combined immunodeficiencies)
- Patients with diseases of the blood that lead to a lack of antibodies and to recurrent infections (Myeloma or chronic lymphatic leukaemia with severe secondary hypogammaglobulinaemia and recurrent infections)
- Patients with congenital AIDS who have repeated bacterial infections

Octagam 50 mg/ml can be used in the following inflammatory diseases:

- In adults or children who do not have a sufficient number of platelets (idiopathic thrombocytopenic purpura), and who have a high risk of bleeding prior to surgery
- In patients with a disease that leads to inflammation of various organs (Kawasaki disease)
- In patients with a disease that can lead to inflammation of certain parts of the nervous system (Guillain Barré syndrome)
- Chronic inflammatory demyelinating polyneuropathy (CIDP, inflammatory disease of certain parts of the nervous system). Only limited experience is available of use of intravenous immunoglobulins in children with CIDP.

2 What you need to know before you use Octagam 50 mg/ml

Do not use Octagam 50 mg/ml:

- if you are allergic to human immunoglobulin or any of the other ingredients contained in Octagam 50 mg/ml (listed in section 6).
- if you have a deficiency of immunoglobulin A (IgA deficiency) with anti-IgA antibodies.

Warnings and precautions

Talk to your doctor or pharmacist before using Octagam 50 mg/ml.

In the case of an adverse reaction, either the rate of administration must be reduced or the infusion must be stopped. The treatment of the adverse event required will depend on the nature and severity of the side effect.

Virus safety
When medicines are made from human blood or plasma, certain measures are put in place to prevent infections being passed on to patients. These include:

- careful selection of blood and plasma donors to make sure those at risk of carrying infections are excluded
- testing of each donation and pools of plasma for signs of virus/infections

- the inclusion of steps in the processing of the blood or plasma that can inactivate or remove viruses.

Despite these measures, when medicines prepared from human blood or plasma are administered, the possibility of passing on infection cannot be totally excluded. This also applies to any unknown or emerging viruses or other types of infections.

The measures taken are considered effective for enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus and hepatitis C virus.

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

Immunoglobulins have not been associated with hepatitis A or parvovirus B19 infections possibly because the antibodies against these infections, which are contained in the product, are protective.

It is strongly recommended that every time that you receive a dose of Octagam 50 mg/ml the name and batch number of the medicine are recorded in order to maintain a a record of the batches used.

Corn allergy

Octagam 50 mg/ml contains maltose, which is derived from corn. Allergic reactions have been reported in association with infusion of other maltose / corn starch related products. If you have a known corn allergy, you should either avoid using Octagam 50 mg/ml or be closely observed for signs and symptoms of hypersensitivity reactions during the infusion of Octagam 50 mg/ml.

Children and adolescents

There are no specific or additional warnings or precautions applicable for children and adolescents.

Other medicines and Octagam 50 mg/ml

The infusion line may be flushed before and after administration of Octagam 50 mg/ml with either normal saline or 5% dextrose in water.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, or if you have received a vaccination in the last three months.

Octagam 50 mg/ml may impair the effect of live viral vaccines such as measles, rubella, mumps and varicella.

After administration of this product, an interval of 3 months should elapse before vaccination with live viral vaccines. In the case of measles, this impairment may persist for up to 1 year.

Inform your doctor that you are taking immunoglobulin when you give a blood sample, as this treatment may affect the results.

Blood Glucose Testing

Some types of blood glucose testing systems (so called glucometers) falsely interpret the maltose contained in Octagam 50 mg/ml 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 hypoglycaemia (i.e. a decreased blood sugar level).

Also, cases of true hypoglycaemia may go untreated if the hypoglycaemic state is masked by falsely elevated glucose readings.

Accordingly, when administering Octagam 50 mg/ml or other maltose containing products, the measurement of blood glucose must be done with a test-system using a glucose-specific method. Systems based on the glucose dehydrogenase pyrroloquinolinequinone (GDH PQQ) or glucose-dye-oxidoreductase methods should not be used.

Review carefully the product information of the blood glucose testing system, including that of the test strips, to determine if the system is appropriate for use with maltose containing parenteral products. If any uncertainty exists, please ask your treating physician to determine if the glucose testing system you are using is appropriate for use with maltose containing parenteral products.

Octagam 50 mg/ml with food, drink and alcohol
No effects have been observed. While using Octagam 50 mg/ml adequate hydration before infusion should be taken into account.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

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 women and breast-feeding mothers. Immunoglobulin preparations 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.

Immunoglobulins are excreted into the milk and may contribute to the transfer of protective antibodies to the newborn.

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

Driving and using machines:
The ability to drive and operate machines may be impaired by some adverse reactions associated with Octagam 50 mg/ml. Patients who experience adverse reactions during treatment should wait for these to resolve before driving or operating machines.

3 How to use Octagam 50 mg/ml

Your doctor will decide if you need Octagam 50 mg/ml and at what dose. Octagam 50 mg/ml is administered as an intravenous infusion (infusion into a vein) by healthcare personnel. The dose and dosage regimen is dependent on the indication and may need to be individualised for each patient.

- If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor as soon as possible if you suffer from any of the serious side effects listed below (**all are very rare** and may affect up to 1 in 10,000 people).
In some cases your doctor may need to interrupt treatment and reduce your dose or stop treatment:

- **Swelling of the face, tongue and windpipe** that can cause great difficulty in breathing
- **A sudden allergic reaction** with shortness of breath, rash, wheezing and drop of blood pressure
- **Stroke** that may cause weakness and / or loss of sensation down one side of the body
- **Heart attack** causing chest pain
- **Blood clot** causing pain and swelling of limbs
- **Blood clot in lung** causing chest pain and breathlessness
- **Severe kidney disorder** that may cause you to not pass urine
- **Non-infectious (aseptic) meningitis** causing severe headache and neck stiffness

If you experience any of the symptoms above, contact your doctor as soon as possible.

The following other side effects have also been reported:

Common side effects (may affect up to 1 in 10 people):
- Hypersensitivity (allergic reaction)
- Headache
- Nausea
- Fever
- Feeling tired
- Skin reactions at injection site

Uncommon side effects (may affect up to 1 in 100 people):
- Eczema

- Back pain
- Chest pain
- Chills

Very rare side effects (may affect up to 1 in 10,000 people):

- haemolytic anaemia (Destruction of and resulting lack of red blood cells; this side effect may be increased in individuals receiving high doses, that have blood group A, B or AB and / or an underlying inflammatory disease)
- Lack of white blood cells
- Fluid overload
- Too low sodium in blood
- Feeling agitated, anxious, confused or nervous
- Migraine
- Speech disorder
- Loss of consciousness
- Dizziness
- Tingling sensation in skin
- Reduced sense of touch or sensation
- Sensitivity to light
- Involuntary muscle contractions
- Impaired vision
- Angina pectoris
- Palpitations
- Changes in heart beat
- Temporary bluish lips or other parts of skin
- Circulatory collapse or shock
- Changes in blood pressure
- Vein inflammation
- Pale color of the skin
- Cough
- Breathing disorders
- Pulmonary oedema (accumulation of fluid in the lung)
- Bronchospasm (difficulty in breathing or wheezing)
- Respiratory failure
- Lack of oxygen in the blood
- Vomiting, diarrhoea, abdominal pain
- Hives, skin itching
- Redness of skin
- Skin rash
- Peeling of the skin
- Inflammation of the skin
- Hair loss
- Pains in joints or muscles
- Muscle weakness or stiffness
- Strong painful muscle contraction

- Neck pain, pain in legs or arms
- Kidney pain
- Swelling of the skin (oedema)
- Flushing, increased sweating
- Chest discomfort
- Flu-like symptoms
- Feeling cold or hot or generally unwell and weak
- Drowsiness
- Burning sensation
- Abnormalities in blood test reports of liver function
- False readings for blood sugar measurements

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

5 How to store Octagam 50 mg/ml

Keep this medicine out of the sight and reach of children.

Do not use Octagam 50 mg/ml after the expiry date which is stated on the label and the carton.

Store below 25°C. Do not freeze. Keep container in the outer carton in order to protect from light.

Do not use Octagam 50 mg/ml if you notice that the solution is cloudy, has deposits or is coloured intensively.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6 Contents of the pack and other information

What Octagam 50 mg/ml contains:

- The active substance is human normal immunoglobulin 50 mg/ml (at least 95% is immunoglobulin G).
- The other ingredients are maltose and water for injections.
- Components used in the packaging of Octagam 50 mg/ml are latex-free.

What Octagam 50 mg/ml looks like and contents of the pack:

Octagam 50 mg/ml is a solution for infusion and is available in vials (2 g/20 ml) or bottles (2.5 g/50 ml, 5 g/100 ml, 10 g/200 ml, 25 g/500 ml).

Pack sizes:

1 g	in	20 ml
2.5 g	in	50 ml
5 g	in	100 ml
10 g	in	200 ml
2 x 10 g	in	2 x 200 ml
3 x 10 g	in	3 x 200 ml
25 g	in	500 ml

Not all pack sizes may be marketed.

The solution is clear or slightly opalescent, colourless or slightly yellow.

Marketing authorisation holder:

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This medicinal product is authorised in the member states of the EEA under the following names:

Finland: OCTAGAM, 50 mg/ml, infuusioneste, liuos

Iceland:	OCTAGAM, 50 mg/ml innrennslislyf, lausn.
Italy:	OCTAGAM, Soluzione per infusione da 50 mg/ml
Spain:	Octagamocta, 50 mg/ml solución para perfusión
United Kingdom:	OCTAGAM 50 mg/ml, solution for infusion

This leaflet was last approved in 05/2017

The following information is intended for medical or healthcare professionals only:

- The product should be brought to room or body temperature before use.
- The solution should be clear to slightly opalescent and colourless to slightly yellow.
- Do not use solutions that are cloudy or have deposits.
- Filtration of Octagam 50 mg/ml is not required
- Any unused product or waste material should be disposed of in accordance with local requirements.
- This medicinal product should not be mixed with other medicinal products.
- The infusion line may be flushed before and after administration of Octagam 50 mg/ml with either normal saline or 5% dextrose in water.