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 children, adolescents (0-18 years) and adults in different groups of patients:

- Patients with inborn deficiency of antibodies (primary immunodeficiency syndromes, such as congenital agammaglobulinaemia and hypogammaglobulinaemia, common variable immunodeficiency, severe combined immunodeficiencies)
- Patients with an acquired deficiency of antibodies (secondary immunodeficiency) due to specific diseases and/or treatments and experiencing severe or recurrent infections

Octagam 50 mg/ml can be used for treatment of susceptible adults, children and adolescents (0-18 years) who have been exposed to measles or are at risk of measles exposure and in whom active vaccination against measles is not indicated or not advised.

Octagam 50 mg/ml can be further used in the treatment of the following autoimmune disorders (immunomodulation):

- in patients with immune thrombocytopenia (ITP), a condition where the platelets get destroyed and are therefore reduced in number, and who have a high risk of bleeding or need to correct the platelet count prior to surgery.
- in patients with Kawasaki disease, a condition that leads to inflammation of various organs.
- in patients with Guillain Barré syndrome, a condition that leads to inflammation of certain parts of the nervous system.
- in patients with chronic inflammatory demyelinating polyneuropathy (CIDP), a disease that leads to chronic inflammation of the peripheral parts of the nervous system which causes muscle weakness and/or numbness mainly in the legs and arms.
- in patients with multifocal motor neuropathy (MMN), a condition that is characterized by slow progressive asymmetrical weakness of limbs without sensory loss.

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) and if you have developed antibodies against immunoglobulins of the type IgA.

Warnings and precautions

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

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 record of the batches used.

Certain adverse reactions may occur more frequently:

- in case of high rate of infusion
- when you receive Octagam 50 mg/ml for the first time or, in rare cases, when there has been a long interval since the previous infusion.
- when you have an untreated infection or an underlying chronic inflammation

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.

Circumstances and conditions increasing the risk of having side effects

- Thromboembolic events such as heart attack, stroke, and obstructions of a deep vein for example in the calves or of a blood vessel in the lung may occur very rarely after administration of Octagam 50 mg/ml. These types of events occur more commonly, although very rarely, in patients with risk factors, such as obesity, advanced age, high blood pressure, diabetes, previous occurrences of such events, prolonged periods of immobilisations, and intake of certain hormones (e.g. the pill). Ensure a balanced fluid intake; moreover Octagam 50 mg/ml should be administered as slowly as possible.
- If you had kidney problems in the past or if you have certain risk factors like diabetes, overweight, or age over 65, Octagam 50 mg/ml should be administered as slowly as possible because cases of acute kidney failure have been reported in patients with such risk factors, although very rarely. Tell your doctor, even when any of the above-mentioned circumstances had happened to you in the past.
- Patients with blood group A, B or AB as well as patients with certain inflammatory conditions have a higher risk of red blood cells being destroyed by the administered immunoglobulins (called haemolysis).

When may slowing or stopping the infusion be required?

- Strong headaches and neck stiffness may rarely occur several hours to 2 days following Octagam 50 mg/ml treatment.
- Allergic reactions are rare, but can induce an anaphylactic shock, even in patients who had tolerated the previous treatments. A sudden fall in blood pressure or shock may be consequences of an anaphylactic reaction.
- In very rare cases transfusion-related acute lung injury (TRALI) can occur after receiving immunoglobulins including Octagam 50 mg/ml. This will lead to non-heart related accumulation of fluid in the air spaces of the lungs. You will recognize TRALI by severe difficulty in breathing, normal heart function and increased body temperature (fever). Symptoms typically appear within 1 to 6 hours after receiving treatment.

Tell your doctor or healthcare professional immediately if you notice such reactions during or after the infusion of Octagam 50 mg/ml. He or she will decide whether to decrease the infusion rate or to stop the infusion completely or if further measures are necessary.

- Sometimes immunoglobulin solutions such as Octagam 50 mg/ml can trigger a decrease in the number of white blood cells. Normally this condition resolves spontaneously within 1-2 weeks.

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.

Children and adolescents

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

Other medicines and Octagam 50 mg/ml

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.

The infusion line may be flushed before and after administration of Octagam 50 mg/ml with either 0.9% saline or 5% dextrose solution.

Concomitant use of loop diuretics should be avoided.

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.

Effects on blood tests

If you have a blood test after receiving Octagam 50 mg/ml, please inform the person taking your blood or your doctor that you have received a human normal immunoglobulin solution, 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 human milk. No negative effects on the breastfed newborns/infants are anticipated.

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

Driving and using machines
Octagam 50 mg/ml has no or negligible influence on the ability to drive and use machines. However, patients who experience adverse reactions during treatment should wait for these to resolve before driving or operating machines.

Octagam 50 mg/ml contains sodium
100 mL of this medicinal product contain 35 mg sodium (main component of cooking/table salt). This is equivalent to 1.75% of the recommended maximum daily dietary intake of sodium for an adult.
To be taken into consideration by patients on a controlled sodium diet.

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.

Use in children and adolescents
The administration (intravenously) of Octagam 50 mg/ml in children and adolescents (0-18 years) does not differ from the administration in adults.

If you receive more Octagam 50 mg/ml than you should
Overdose is very unlikely to occur because Octagam 50 mg/ml is usually administered under medical supervision. If, in spite of this, you receive more Octagam 50 mg/ml than you should, your blood may become too thick (hyperviscous) which might increase the risk of developing blood clots. This may happen particularly if you are a patient at risk, for example if you are elderly or if you suffer from a heart or kidney disease. Make sure you are well hydrated. Tell your doctor if you are known to have medical problems.

If you forgot to use Octagam 50 mg/ml
Please talk to your doctor and discuss on how to further proceed.

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 infusions).
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
- **Anaemia** causing shortness of breath or looking pale
- **Blood clot in lung** causing chest pain and breathlessness
- **Severe kidney disorder** that may cause you to not pass urine
- A **lung condition** referred to as transfusion-related acute lung injury (TRALI) causing difficulty in breathing, bluish skin, fever, a decrease in blood pressure
- **Severe headache** in combination with any of the following symptoms as neck stiffness, sleepiness, fever, light sensitivity, nausea, vomiting (this can be signs of meningitis).

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 infusions):
- Hypersensitivity (allergic reaction)
- Headache

Uncommon side effects (may affect up to 1 in 100 infusions):
- Lack of white blood cells
- Changes in heart beat
- Changes in blood pressure
- Vomiting
- Back pain
- Chest pain
- Chills
- Nausea
- Fever
- Feeling tired
- Skin reactions at injection site
- Abnormalities in blood test reports of liver function

Further side effects that did not occur in clinical studies, but have also been reported, are:
- 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
- Temporary bluish lips or other parts of skin
- Circulatory collapse or shock
- 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
- 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
- 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.

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

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.

After first opening, the medicine should be used immediately.

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 (human antibodies) 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 (1 g/20 ml) and 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

OCTAPHARMA Limited
Glassworks House
32 Shudehill
Manchester M4 1EZ
United Kingdom

Manufacturers

Octapharma Pharmazeutika Produktionsges.m.b.H.
Oberlaaer Strasse 235, A-1100 Vienna, Austria

Octapharma S.A.S.
70-72 rue de Marèchal Foch, BP 33, F-67380 Lingolsheim, France

Octapharma AB
SE-112 75 Stockholm, Sweden

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Hungary, Iceland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Norway, Portugal, Romania, Slovenia, Sweden, United Kingdom (Northern Ireland):	Octagam 50 mg/ml
Austria, Bulgaria, Germany, Poland, Slovakia:	Octagam 5%
Spain:	Octagamocta 50 mg/ml

This leaflet was last approved in 07/2024

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.
- 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 0.9% saline or 5% dextrose solution.