PACKAGE LEAFLET: INFORMATION FOR THE USER

GAMTEN, 100 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 Gamten **is** and what it is used for

What Gamten is

Gamten 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. Gamten 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.

Gamten has a broad spectrum of antibodies against various infectious agents.

What Gamten is used for

Gamten 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

Gamten 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.
- in adult patients with active dermatomyositis (DM), a condition that leads to muscle inflammation and changes in your skin. Typical symptoms are progressive symmetric muscles weakness as well as typical changes of the skin such as rash on different body parts (e.g. eyelids, cheeks, nose, back, elbows, knuckles) and a scaly, rough and dry skin. Gamten can be used in patients who are treated with drugs that suppress the immune system, such as corticosteroids, or if these drugs are contraindicated or not well tolerated.

2 What you need to know before you use Gamten

Do not use Gamten:

- if you are allergic to human immunoglobulin or any of the other ingredients contained in Gamten (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 Gamten.

It is strongly recommended that every time you receive a dose of Gamten the name and batch number of the product 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 Gamten 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 Gamten. These types of events occur more commonly, although very rarely, in patients with risk factors, such as obesity, advanced age, high blood pressure, diabetes, dermatomyositis, previous occurrences of such events, prolonged periods of immobilisations, and intake of certain hormones (e.g. the pill). Ensure a balanced fluid intake; moreover Gamten 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, Gamten should be administered as slowly as possible because cases of acute kidney failure have been reported in patients, although very rarely, with such risk factors. 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 Gamten treatment.
- Allergic reactions are rare, but can induce an anaphylactic shock, even in patients who had tolerated the previous treatments.
- In very rare cases transfusion-related acute lung injury (TRALI) can occur after receiving immunoglobulins including Gamten. 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 Gamten. 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 Gamten 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
- steps included by the manufacturers 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 encapsulated viruses such as human immunodeficiency virus (HIV), hepatitis B virus and hepatitis C virus.

The measures taken may be of limited value against non-encapsulated 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 Gamten

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

Concomitant use of loop diuretics should be avoided.

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.

Gamten may impair the effect 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.

Effects on blood tests

If you have a blood test after receiving Gamten, 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 Gamten 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 Gamten 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.

Gamten with food, drink and alcohol
No effects have been observed. While using Gamten 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
Gamten 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.

Gamten contains sodium
100 mL of this medicinal product contains 69 mg sodium (main component of cooking/table salt). This is equivalent to 3.45% of the recommended maximum daily intake of 2 g sodium for an adult.
To be taken into consideration by patients on a controlled sodium diet.

3 How to use Gamten

Your doctor will decide if you need Gamten and at what dose. Gamten 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 Gamten in children and adolescents (0-18 years) does not differ from the administration in adults.

4 Possible side effects

Like all medicines, this type of 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
- **Blood clot in lung** causing chest pain and breathlessness
- **Anaemia** causing shortness of breath or looking pale
- **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 with this medicine:

Common side effects (may affect up to 1 in 10 infusions):
- Hypersensitivity (allergic reaction)
- Headache
- Nausea
- Changes in blood pressure
- Fever

Uncommon side effects (may affect up to 1 in 100 infusions):
- Lack of different types of blood cells
- Changes in heart beat
- Vomiting
- Stroke
- Dizziness
- Tingling, prickling sensation in skin

- Shivering
- Blurred vision
- Clots in blood vessels
- Blockage of a deep vein
- Blockage of an artery in the lung
- Back pain
- Chest pain
- Pains in joints or muscles
- Involuntary muscles contraction
- Pain in legs or arms
- Breathing disorders
- Chills
- Feeling tired, generally unwell or weak
- Fluid in tissues of extremities
- Skin reactions at injection site
- Abnormalities in blood test reports (i.e. of liver function, or red blood cells)

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
- Reduced sense of touch or sensation
- Sensitivity to light
- 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
- 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
- Muscle weakness or stiffness
- Strong painful muscle contraction
- Neck pain

- Kidney pain
- Swelling of the skin (oedema)
- Flushing, increased sweating
- Chest discomfort
- Flu-like symptoms
- Feeling cold or hot
- 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 (for details see below). 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 or search for MHRA Yellow Card in the Google Play or Apple App Store

5 How to store Gamten

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

Do not use Gamten after the expiry date which is stated on the label and the carton.

Store in a refrigerator (2°C – 8°C). Keep the container in the outer carton in order to protect from light. Do not freeze.

The product may be removed from the refrigerator for a single period of up to 9 months (without exceeding the expiry date) and stored at a temperature ≤ 25°C. At the end of this period, the product should not be refrigerated again and should be disposed of. The date at which the product was taken out of the refrigerator should be recorded on the outer carton.

After first opening, the product should be used immediately.

Do not use Gamten 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 Gamten contains

- The active substance is human normal immunoglobulin (human antibodies) 100 mg/ml (at least 95% is immunoglobulin G).
- The other ingredients are maltose and water for injections.

What Gamten looks like and contents of the pack
Gamten *is* a solution for infusion and is available in vials (2g/20 ml) or bottles (5g/50 ml, 6g/60 ml, 10g/100 ml, 20g/200 ml, 30g/300 ml).

Pack sizes:

2 g	in	20 ml
5 g	in	50 ml
6 g	in	60 ml
10 g	in	100 ml
20 g	in	200 ml
3 x 10 g	in	3 x 100 ml
3 x 20 g	in	3 x 200 ml
30 g	in	300 ml

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

Not all pack sizes may be marketed.

Marketing authorisation holder
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United Kingdom

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

Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Iceland, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Sweden, United Kingdom:	Octagam
Italy:	Gamten
Spain	Octagamocta

This leaflet was last approved in February 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.
- In order to infuse any product that may remain in the infusion tubing at the end of the infusion the tubing may be flushed with either 0.9% saline or 5% dextrose solution.