

Package leaflet: Information for the user

Gammaplex 5% w/v solution for infusion

human normal immunoglobulin

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, pharmacist or nurse.
- This medicine has been prescribed for you only. 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Gammaplex is and what it is used for
2. What you need to know before you use Gammaplex
3. How to use Gammaplex
4. Possible side effects
5. How to store Gammaplex
6. Contents of the pack and other information

1. What Gammaplex is and what it is used for

Gammaplex is a solution containing the active substance called human normal immunoglobulin (a protein in the body used to fight infections) which is obtained from blood plasma from screened donors. These donors are selected from carefully screened and healthy donors from the USA. The product is given by injection into a vein (intravenous infusion). It can be given in a hospital or for use at home and is only available on a doctor's prescription.

Gammaplex is used to treat patients who require antibody replacement because they were born with an inability to produce antibodies (primary immunodeficiencies).

Gammaplex is also used to replace antibodies in secondary immunodeficiencies with severe or recurrent infections, ineffective antimicrobial treatment and either proven specific antibody failure or low serum immunoglobulin G level.

Gammaplex is also used for the treatment of certain inflammatory disorders:

- Primary immune thrombocytopenia (ITP, a blood platelet disorder), in patients at high risk of bleeding or requiring surgery
- Kawasaki disease (an acute disorder of the blood vessels and heart in children)
- Guillain Barré syndrome (an acute disorder of the peripheral nerves)
- Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP, a nervous system disorder)
- Multifocal motor neuropathy (MMN, progressive dysfunction of the peripheral nerves, typically causing numbness or weakness).

Gammaplex is used to treat adults, children and adolescents (aged 0-18 years).

2. What you need to know before you use Gammaplex

Do not use Gammaplex

- if you suffer from hereditary fructose intolerance,
- for babies and young children who may have a fruit sugar intolerance,

- if you are allergic to human normal immunoglobulin or any of the other ingredients of this medicine (listed in Section 6). If you do experience an allergic reaction, seek medical attention immediately,
- if you have developed antibodies to IgA. Your doctor will advise you if this affects you.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Gammaplex if any of the following conditions applies to you:

- fruit sugar intolerance,
- if you have a kidney disorder
- if you have diabetes
- if you are overweight
- if you have high blood pressure
- if you have ever had a stroke, heart attack or other clotting complaint (now or in the past)

You may need to be monitored closely during treatment and the dose may have to be altered.

With immunoglobulin treatments, you may get lung damage related to the treatment called Transfusion Related Acute Lung Injury (TRALI). If you get shortness of breath and find yourself having to breathe rapidly during or within several hours of your infusion, tell your doctor or nurse immediately as these symptoms may need urgent treatment.

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
- the 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 given, 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 viruses such as human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV), and for hepatitis A (HAV) and parvovirus B19 viruses. 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 the name and batch number of the medicine are recorded every time you receive a dose of Gammaplex in order to maintain a record of the batches used.

Children and adolescents

The listed warnings and precautions for adults also apply to children and adolescents (aged 0-18 years).

Other medicines and Gammaplex

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Vaccinations

Immunoglobulin infusions may also interfere with immunisation with certain virus vaccines such as measles, rubella, mumps and varicella for a period of at least 6 weeks and up to 3 months. In the case of measles, this impairment may persist for up to a year. If you need a blood test during this period, tell your doctor when you last had an injection of Gammaplex, as false positive results may occur with certain tests. This medicine will raise the level of various antibodies in your blood for several weeks or longer.

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 for advice before using this medicine.

Driving and using machines

Some side effects of Gammaplex may affect your ability to drive or operate machinery. Wait for side effects to resolve before you drive or operate machines.

Gammaplex contains sorbitol and sodium

Sorbitol is a source of fructose. If you (or your child) have hereditary fructose intolerance (HFI), a rare genetic disorder, you (or your child) must not receive this medicine. Patients with HFI cannot break down fructose, which may cause serious side effects.

You must tell your doctor before receiving this medicine if you (or your child) have HFI or if your child can no longer take sweet foods or drinks because they feel sick, vomit or get unpleasant effects such as bloating, stomach cramps or diarrhoea.

This medicine contains up to 0.06 mmol (1.29 mg) sodium per millilitre of solution. Therefore, according to the dose your doctor has advised, you will receive 5.16 – 51.6 mg sodium per kg of body weight. This range is equivalent to 0.26 – 2.6% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Gammaplex

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Do not exceed the recommended dose. See below for full dosage recommendations. Your doctor will decide the appropriate dose. Do not add any other medicines or fluids to Gammaplex.

The medicine is given by intravenous injection (infusion) using a giving set which your doctor or nurse will provide. The maximum safe rate of infusion is determined by your body weight. An infusion rate of 0.6 - 1.2 ml/kg/hour is recommended for the first 15 minutes, gradually increasing it to 4.8 ml/kg/hour.

To reduce the risk of side effects, the infusion rate in the first 15 minutes must be low (0.6 - 1.2 ml/kg/hour). Some severe side effects may be caused by injecting the product too quickly.

The recommended infusion rate must be checked closely and you must be carefully observed for any symptoms throughout this period. **If you feel unwell, tell your doctor and the infusion will either be slowed or stopped until you feel better.**

You should remain with another person for at least 20 minutes after the infusion is complete or for an hour if it is the first time you have had this product.

Bring the medicine to room temperature for at least 2 hours before infusion. **Do not use** if there are any particles in the medicine or it is discoloured. Contact your doctor if you are not sure if your medicine is fit for use.

The product does not contain any additives to prevent the growth of germs once it has been opened. Therefore the infusion should begin **immediately** after piercing the cap.

This product is for single injection only. Safely throw away any used materials or unused solution. To help you, your doctor will provide instructions and a box.

If you receive more Gammaplex than you should

If you receive more Gammaplex than you should there is no cause for alarm. However, if you feel unwell afterwards or have any discomfort, tell your doctor.

If you forget to use Gammaplex

Tell your doctor or nurse if you have missed a dose. Do not take a double dose to make up for a forgotten dose.

If you stop using Gammaplex

You should consult your doctor if you begin to feel unwell. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Tell your doctor if you experience any of the side effects listed in this section, because your treatment may need to be changed or stopped.

Some side effects can be serious and may need medical attention. Tell your doctor immediately if you notice any of the following:

- sudden drop in blood pressure, making you feel very dizzy or faint
- severe allergic reaction causing an itchy, raised skin rash or swelling of your eyes, face, mouth or throat
- unusually pale or yellow skin, unusually dark urine
- sudden shortness of breath, difficulty breathing, chest tightness or pain
- sudden severe headache, vision changes or confusion
- difficulties with speech, balance or movement
- throbbing pain or ache in your leg, with swollen or firm, tender skin
- swelling of the hands or feet, urinating less than normal or feeling unusually tired
- flu-like symptoms with headache, fever, stiff neck, feeling or being sick

Other possible side effectsVery common (may affect more than 1 in 10 people)

- headache
- high temperature

Common (may affect up to 1 in 10 people)

- vomiting or feeling sick
- dizziness or vertigo
- body pain, back pain or neck pain
- muscle pain or spasms
- joint pain
- raised or lowered blood pressure
- raised pulse rate
- palpitations
- diarrhoea
- stomach pain
- nose congestion
- tiredness
- chills
- chest discomfort/pain
- pain, redness or inflammation at infusion site
- fluid retention

- blood test (Coombs') positive
- dehydration
- anaemia

Uncommon (may affect up to 1 in 100 people)

- weakness
- wheeze
- migraine
- pins and needles or numbness
- muscle or joint stiffness
- decreased appetite
- sleeping difficulties
- ringing in ears
- hot flushes
- sore throat
- mouth ulcers
- skin rash or itching
- nose bleeds
- bloating
- – constipation
- increased white blood cell count (shown by blood test)
- antibody against red blood cells (shown by blood test)
- positive urine test for haemosiderin, an iron storage compound (related to anaemia)
- iron deficiency
- stomach acidity reduced

Reporting of side effects

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 medicine.

5. How to store Gammalex

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

The medicine should be stored in its carton, between 2°C and 25°C.

Do not freeze.

Do not use this medicine if you notice the solution is cloudy or has deposits.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Disposal

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

6. Contents of the pack and other information

What Gammalex contains

The active substance is human normal immunoglobulin, mainly immunoglobulin G (IgG) and is obtained from blood plasma from screened donors. These donors are selected from the USA.

The other ingredients are D-sorbitol, glycine, sodium chloride, sodium acetate and polysorbate 80 (see Section 2 “Gammaplex contains sorbitol and sodium”).

Gammaplex is slightly acidic, but this will not have any unpleasant effects as your blood will neutralise it rapidly.

The IgA content of Gammaplex is less than 10 micrograms/ml (typically about 4 micrograms/ml).

Gammaplex has a composition of the different types of IgG immunoglobulins similar to that in blood.

What Gammaplex looks like and contents of the pack

Gammaplex is a clear or slightly pearl-like (opalescent), colourless or pale yellow liquid.

This product comes in 2.5 g, 5 g, 10 g and 20 g dose sizes.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Bio Products Laboratory Ltd., Dagger Lane, Elstree, Hertfordshire, WD6 3BX, United Kingdom

Manufacturer

Bio Products Laboratory Ltd., Dagger Lane, Elstree, Borehamwood, WD6 3BX, United Kingdom

This leaflet was last revised in December 2021

Other sources of information

For further information or if you have any questions about the use of this product, please contact BPL via the Medical Department at the address above or through medinfo@bpl.co.uk.