



GAMMAPLEX® 2.5 G, 5 G, 10 G and 20 G. 5% W/V SOLUTION FOR INFUSION HUMAN NORMAL IMMUNOGLOBULIN

READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START USING THIS MEDICINE.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In This Leaflet:

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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 several illnesses. Your doctor will advise you what you are receiving Gammaplex® for.

This medicine is used to replace antibodies which are missing from your body in primary antibody deficiencies (lack of certain proteins protective against infection that you may either have been born with or may develop during life) such as:

- agammaglobulinaemia (deficiency of gamma globulins in the blood),
- hypogammaglobulinaemia (low levels of immunoglobulin G (IgG), with or without low IgA and/or IgM),
- common variable immunodeficiency (failure of the immune system to produce antibodies against infections),
- severe combined immunodeficiency (a severe genetic disorder of the immune system making you susceptible to infections),
- Wiskott Aldrich syndrome (hereditary disorder with signs of eczema, recurring infections, and a decrease in the number of white blood cells).

Gammaplex® is also used to replace antibodies in secondary antibody deficiencies caused by:

- chronic lymphocytic leukaemia (cancer of the blood where too many white blood cells are produced),
- some other bone marrow cancers,
- AIDS in children born with the disease, when repeated infections occur.

Gammaplex® is also used for the treatment of:

- Idiopathic thrombocytopenic purpura (ITP, a blood platelet disorder),
- Kawasaki disease (disorder of the blood vessels and heart in children),
- Guillain Barré syndrome (disorder of peripheral nerves),
- Bone marrow transplant, as an immunoglobulin supplement.

2. BEFORE YOU ARE GIVEN GAMMAPLEX®

Do not allow Gammaplex® to be given to you if you:

- are allergic to human normal immunoglobulin or any of the other ingredients of Gammaplex® (see end of Section 2 and Section 6). If you do experience an allergic reaction, seek medical attention immediately.
- have developed antibodies to IgA. Your doctor will advise you if this affects you.

Take special care with Gammaplex®

You must tell your doctor **before** receiving Gammaplex® if any of the following conditions applies to you. You may need to be monitored closely during treatment and the dose may have to be altered.

- diabetes
- obesity
- kidney disorder
- stroke (now or in the past)
- heart complaint (now or in the past)
- are elderly
- taking other medicines
- pregnant or breast-feeding.

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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including any that you have bought yourself from a chemist without a prescription. No other medicines or fluids should be added to this product, as their effects on the product have not been established.

Pregnancy and breast-feeding

If you are pregnant, likely to become pregnant or are breast-feeding, you must tell your doctor before receiving Gammaplex®.

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.

What you need to know before you use Gammaplex®

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 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, and for the non-enveloped hepatitis A 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 every time you receive a dose of Gammaplex® the name and batch number of the medicine are recorded in order to maintain a record of the batches used.

Important information about some of the ingredients of Gammaplex®

D-sorbitol and sodium are ingredients in this product.

If you know you are unable to digest fructose (a certain type of sugar, sometimes called fruit sugar) then do not use Gammaplex. Also, this medicine should not be used in babies or very young children until they are known to be able to digest fructose. Sucrose (Table sugar) contains fructose.

3. HOW YOU WILL BE GIVEN GAMMAPLEX®

Always use Gammaplex® exactly as your doctor has told you. You should check with your doctor or pharmacist 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 0.01 - 0.02 mL/kg/minute is recommended for the first 15 minutes, gradually increasing it to 0.08 mL/kg/minute.

To reduce the risk of side effects, the infusion rate in the first 15 minutes must be low (0.01 - 0.02 mL/kg/minute). 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.

Dosage recommendations:

- **antibody deficiency disease:** the dosage is at first 0.4 - 0.8 g/kg body weight, then 0.2 - 0.8 g/kg body weight every 3 to 4 weeks, depending on your clinical response and measurements of immunoglobulins in the bloodstream.
- **bone marrow cancers (including leukaemia) and children born with AIDS resulting in antibody deficiencies:** 0.2 - 0.4 g/kg body weight every 3 to 4 weeks.
- **Idiopathic thrombocytopenic purpura (ITP):** 0.8 - 1 g/kg body weight as a single dose, sometimes repeated within 3 days. A dose of 0.4 g/kg may be administered daily for 2 - 5 days.
- **Guillain Barré syndrome:** 0.4 g/kg/day for 5 days.
- **Kawasaki disease:** 1.6 to 2 g/kg body weight split into several doses over 2 - 5 days or 2 g/kg body weight as a single dose. Aspirin should usually be given as well. Your doctor will decide the appropriate dose and whether you should take aspirin.
- **After bone marrow transplant:** 0.2 - 0.4 g/kg body weight every 3 to 4 weeks.

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 use more Gammaplex® than you should

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Gammaplex® can cause side effects, although not everybody gets them. If you feel unwell, you must tell your doctor immediately.

The risk of side effects can be minimised by making sure that the infusion rate in the first 15 minutes is low (0.01 - 0.02 mL/kg/minute) (see Section 3 "How you will be given Gammaplex®").

The following side effects have also been reported to occur:

Very common side effects (affecting more than 1 in 10 people)

- headache

Common side effects (affecting less than 1 in 10 and more than 1 in 100 people)

- vomiting or feeling sick
- high temperature
- tiredness or weakness
- dizziness or vertigo
- body pain, back pain or neck pain
- muscle pain or spasms
- joint pain
- raised blood pressure
- palpitations
- diarrhoea
- stomach pain or acidity
- nose congestion
- chills
- skin rash or itching
- chest discomfort
- pain or inflammation at infusion site
- fluid retention
- pins & needles or numbness
- blood test (Coombs') positive

Uncommon side effects (affecting less than 1 in 100 and more than 1 in 1,000 people)

- blood clots
- dehydration
- wheeze
- migraine
- muscle or joint stiffness
- decreased appetite
- insomnia
- ringing in ears
- hot flushes
- sore throat

- mouth ulcers
- nose bleeds
- bloating
- constipation
- raised pulse rate
- increased white blood cell count (shown by blood test)
- antibody positive (shown by blood test)
- positive urine test for haemosiderin, an iron storage compound (related to anaemia)
- anaemia
- iron deficiency

Rare side effects (affecting less than 1 in 1,000 and more than 1 in 10,000 people)

- sudden fall in blood pressure which could be serious
- severe allergic reaction that may cause difficulty in breathing or swallowing
- kidney failure

If you are using this medicine at home and you feel unwell during the infusion, stop the infusion and contact your doctor immediately. If you feel unwell during an infusion in hospital tell the doctor or nurse immediately. The rate of infusion will probably then be slowed until you feel better. The rate of infusion may then be slowly increased to half that achieved when you started to feel unwell. If you still feel unwell, the infusion should be stopped, but may be resumed after about an hour when you are feeling better.

Please remember:

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. HOW TO STORE GAMMAPLEX®

Keep Gammaplex® out of the reach and sight of children.

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

DO NOT FREEZE.

Do not use Gammaplex® if you notice the solution is cloudy or has deposits.

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

The condition of date-expired or incorrectly stored product cannot be guaranteed.

Disposal

Medicines should not be disposed of via wastewater or household waste. To help you, your doctor will provide instructions and a box. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Gammaplex® 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 also end of Section 2 "Important information about some of the ingredients of Gammaplex®").

Gammaplex® is slightly acidic, but this will not have any unpleasant effects as your blood will neutralise it rapidly. The maximum amount of sodium is 50 mmol/L.

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 sterile, colourless liquid.

This product comes in 2.5 g, 5 g, 10 g and 20 g dose sizes, with a sling to hold the bottle during infusion.

Marketing Authorisation Holder, and manufacturer

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Marketing Authorisation Number
PL 08801/0053

Date of Revision of Text
November 2012

VSL7

For further information or if you have any questions about the use of this product, please contact BPL via the Marketing Department at the address above or by e-mail: info@bpl.co.uk.



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