

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET: INFORMATION FOR THE USER****VIGAM LIQUID 2.5 G, 5 G and 10 G  
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 Vigam Liquid is and what it is used for**
- 2. What you need to know before you use Vigam Liquid**
- 3. How to use Vigam Liquid**
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**1. What Vigam Liquid is and what it is used for**

Vigam Liquid 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 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.

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), 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).

Vigam Liquid is also used to replace antibodies in secondary antibody deficiencies caused by:

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

Vigam Liquid 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. What you need to know before you use Vigam Liquid****Do not use Vigam Liquid:**

- 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 lack IgA or 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 Vigam Liquid if any of the following conditions apply to you;

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

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

Immunoglobulin infusions may also interfere with immunisation with certain virus vaccines such as measles, rubella, mumps, varicella and yellow fever, 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 Vigam Liquid, 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.

#### **Other medicines and Vigam Liquid**

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

#### **Pregnancy, breast-feeding and fertility**

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

#### **Driving and using machines**

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

#### **Vigam Liquid contains sucrose and sodium .**

If you have been told that you have an intolerance to some sugars or are on a sodium-controlled diet, tell the doctor before he/she gives you the infusion.

#### **Please note**

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. 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 you receive a dose of Vigam Liquid the name and batch number of the medicine are recorded in order to maintain a record of the batches used.

### 3. How to use Vigam Liquid

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 Vigam Liquid.

#### Dosage recommendations:

- **antibody deficiency disease:** the dosage is initially 0.4 - 0.8 g/kg body weight, then at least 0.2 g/kg body weight every 2 - 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 3 days later. A dose of 0.4 g/kg may be administered for 2 - 5 days.
- **Guillain Barré syndrome:** 0.4 g/kg/day for 3 - 7 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.
- Before and after **bone marrow transplant:** as required, initially 0.5 g/kg body weight/week. If antibody levels remain low this dose may be given monthly until no longer required.

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 medicine is given by intravenous injection (infusion) using a recommended 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 30 minutes, gradually increasing it to 0.04 mL/kg/minute up to a maximum of 3 mL/ minute.

**To reduce the risk of side effects**, the infusion rate in the first 30 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.

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, tell the doctor or nurse. The rate of infusion will probably then be slowed until you feel better. The rate of infusion may then be cautiously increased. If you feel particularly unwell during an infusion, the infusion may be stopped, but it may be resumed when you are feeling better.

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 or **within 2 hours**.

This product is for single injection only. Safely throw away any used materials or unused solution. Your doctor will do this.

#### If you use more Vigam Liquid than you should

If you use more Vigam Liquid 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 Vigam Liquid

Do not take a double dose to make up for a forgotten dose.

**If you stop using Vigam Liquid**

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. 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 30 minutes is low (0.01 - 0.02 mL/kg/minute) (see Section 3 "How to use Vigam Liquid").

Some side effects may persist for several hours to a few days after receiving the infusion. These include:

- severe headache
- dislike of bright light
- vomiting
- fever
- stiff neck
- chills
- backache
- shortness of breath
- skin and other allergic reactions

If you have a history of migraine and/or receiving large doses you may be more likely to develop these symptoms. You should tell your doctor if you suffer from migraines. No longterm damage is known to occur.

**The following side effects have also been reported to occur:**

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

- fever

**Common side effects** (affecting less than 1 in 10 people)

- headache
- sore throat
- joint pain
- feeling sick
- being sick
- feeling drowsy
- spotty rash
- itchy reddened skin
- tiredness
- scaly inflammation of the skin
- pain and inflammation at the injection site
- high or low blood pressure

**Rare side effects** (occurring in less than 1 in 1,000 and more than 1 in 10,000 people):

- sudden fall in blood pressure, which could lead to shock;
- some red blood cells may be destroyed;
- kidney function may be reduced.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

**Reporting of side effects**

« If you get any side effects, talk to your <doctor> <or> <,> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the Pharmaceutical Services, Ministry of Health, CY-1475, [www.moh.gov.cy/phs](http://www.moh.gov.cy/phs)  
Fax: + 35722608649. By reporting side effects you can help provide more information on the safety of this medicine.»

**5. How to store Vigam Liquid**

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

The medicine should be stored in the dark in its carton, between 2°C and 8°C. DO NOT FREEZE. Storage for a short period of up to 3 months at 25°C is possible within the storage date printed on the label.

**Do not use** Vigam Liquid 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 medicines you no longer use. These measures will help protect the environment.

**6. Contents of pack and other information****What Vigam Liquid 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 human albumin, sucrose, glycine, sodium acetate and sodium-n-octanoate added as stabilisers (*see also end of Section 2 "Vigam Liquid contains sucrose and sodium"*).

Vigam Liquid is slightly acidic, but this will not have any unpleasant effects as your blood will neutralise it rapidly. The maximum amount of sodium is 160 mmol/L.

The IgA content of Vigam Liquid is not greater than 0.02% of the total protein content.

Vigam Liquid has a composition of the different types of immunoglobulins similar to that in blood.

**What Vigam Liquid looks like and contents of the pack**

Vigam Liquid is a sterile, colourless to pale amber or pale green liquid.

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

**Marketing Authorisation Holder and Manufacturer**

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**Marketing Authorisation Number**

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**Other sources of information**

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 through [medinfo@bpl.co.uk](mailto:medinfo@bpl.co.uk).