Package leaflet: Information for the user

Gammanorm, 165 mg/mL, solution for injection
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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Gammanorm is and what it is used for

Gammanorm contains human normal immunoglobulins which are antibodies against bacteria and viruses. Antibodies protect the body and increase its resistance to infections. The purpose of this treatment is to attain normal antibody levels in the blood.

Gammanorm is used as replacement therapy in adults, children and adolescents (0-18 years) in:
- Patients who are born with a reduced ability or inability to produce immunoglobulins (primary immunodeficiencies).
- Patients with chronic lymphocytic leukaemia, a certain kind of blood cancer that leads to a lack of antibodies and to recurrent infections, when antibiotics have failed or may not be given.
- Patients with multiple myeloma, another kind of blood cancer that leads to a lack of antibodies and to recurrent infections
- Patients with lack of antibodies and recurrent infections before and after a bone marrow cell transplantation

2. What you need to know before you use Gammanorm

Do not use Gammanorm:
- if you are allergic to human normal immunoglobulin or any of the other ingredients of this medicine (listed in section 6).
- intravenously (Gammanorm must not be administered into a vein).

Warnings and precautions:
Talk to your doctor or pharmacist before using Gammanorm:
- if you have any other illness.
- if you have diabetes and if you have ever had a vascular disease or a blood clot.
- if you have an increased risk of blood clots.
- if you are bedridden for a long time.

Inform your doctor that you are taking immunoglobulin when you give a blood sample, as this treatment may affect the results.

If Gammanorm is accidentally administered into a blood vessel, you could develop shock. For instructions on how to avoid injecting Gammanorm into a blood vessel see section "3. How to use Gammanorm" under subsection "Handling instructions" (below).

Certain side effects may occur more often in people who are receiving Gammanorm for the first time or, in rare cases, when changing human normal immunoglobulin products, or when a longer period of time has passed since the previous 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 the 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 viruses/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 Gammanorm the name and batch number of the product are recorded in order to maintain a record of the batches used.

Other medicines and Gammanorm
- Inform your doctor or pharmacist if you are taking, or have recently taken any other medicines, even over-the-counter ones, or if you have received a vaccination in the last three months.

- Gammanorm may weaken the effect of vaccines such as measles, rubella, mumps, and chicken pox. Following treatment with Gammanorm, three months should have elapsed before you are vaccinated with any of these vaccines. Where measles vaccine is concerned, you may need to wait up to a year following treatment with Gammanorm. It is therefore important that the doctor carrying out the vaccination is aware that you are having, or have had treatment with Gammanorm.

Pregnancy and breastfeeding:
There is limited experience of usage of Gammanorm during pregnancy and breastfeeding. You should therefore consult your doctor before using Gammanorm when you are pregnant or breastfeeding.
Immunoglobulins are excreted into the milk and may contribute to the transfer of protective antibodies to the newborn.

Driving and using machines:
The ability to drive and operate machines may be impaired by some adverse reactions associated with Gammanorm. If you experience adverse reactions during treatment you should wait for these to resolve before driving or operating machines.

Gammanorm contains Sodium
This medicine contains 25 mg (or 1.1 mmol) sodium (main component of cooking/table salt) in each vial of 10 mL, and 60 mg (or 2.61 mmol) sodium in each vial of 24 mL. This is equivalent to 1.25%, and 3%, respectively 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 Gammanorm

Treatment will be started off by your doctor who should be experienced in providing guidance for home treatment with subcutaneous immunoglobulin. Your doctor will ensure that you receive training and clear information on how to administer Gammanorm (e.g. using the infusion pump and/or syringe, and on infusion technique), keeping a treatment diary, and what action to take in the event of serious side effects. As soon as you are able to treat yourself, and if no side effects have arisen during treatment, your doctor may allow you to continue treatment at home.

Your individual dosage and infusion speed will be determined by your doctor, who will adapt the dose specifically for you. Always follow your doctor’s instructions.

This product should be administered subcutaneously (under the skin).
Instructions:

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

The product should be at room or body temperature prior to use.

The solution should be clear or slightly opalescent and colourless or pale yellow or light brown. Do not use solution that is cloudy, contains particles, or has deposits.

Handling instructions:

- Remove the protective cap from the vial and wipe the rubber stopper with alcohol.
- To withdraw Gammanorm, use a sterile syringe and a needle or a transfer device (e.g. Minispike® or Medimop® vial adapter).
- Inject an amount of air into the vial that is equivalent to the amount of Gammanorm to be withdrawn. Then withdraw Gammanorm from the vial. If multiple vials are required to achieve the desired amount of Gammanorm, repeat this step.
- If using a pump: follow the manufacturer's instructions for preparing the pump (priming). In order to ensure that no air is left in the tubing fill the tubing/needle with Gammanorm.
- Clean the injection site(s) (e.g. lower abdomen, thigh) with antiseptic solution.
- Grasp the skin between two fingers and insert the needle into the subcutaneous tissue as trained by your doctor.
- *Gammanorm must not be injected into a blood vessel.* Test that no blood vessel has been accidentally hit by gently pulling back on the syringe plunger, and looking to see if any blood is flowing back into the tubing. If you see any blood, remove and discard the needle and tubing. Repeat the priming and needle injection steps using a new needle, tubing and a new injection site.
- Secure the needle in place by applying sterile gauze or transparent dressing.

- **<u>Infusion of Gammanorm using a pump:</u>**
  - Follow the manufacturer's instructions for the pump.
  - It is recommended to use an initial administration speed of 15 mL/hour/site. If well tolerated, for subsequent infusions, the flow rate may be gradually increased at a rate of 1-2 mL/hour/site to 25 mL/hour/site as tolerated. The maximum flow rate administered, if tolerated, can be 100mL/hour for all sites combined.
  - In infants and children, the injection site may be changed after 5 – 15 mL.
  - In adults the injection site may be changed according to own preference. The maximum volume to be infused per site should not exceed 25 mL during the first 10 infusions. Thereafter the volume per site may be gradually increased to 35 mL, if tolerated.
  - Multiple injection sites can be used simultaneously. Injection sites should be at least 5 cm apart.

- **<u>Infusion of Gammanorm using a syringe:</u>**
  - You may use a "Butterfly" type catheter, which allows for faster administration. According to the application system you will use, the procedure may differ in some minor details.
  - You may only use one injection site at a time. It might be necessary to administer the daily dose at more than one injection site.
  - Start pushing on the plunger: subcutaneous immunoglobulin is viscous and will resist your pushing.
  - You should choose a speed of injection to suit what you are comfortable with. The recommended maximum infusion rate is approximately 1–2 mL/minute. Take your time: the injection should not be painful. Some injection sites will tolerate larger volumes than others. If necessary, change to a new injection site.

    - In infants and children, the maximum volume to be infused per injection site should not exceed 5–15 mL.
    - In adults, the maximum volume to be infused per injection site should not exceed 25 mL.
    - The dosage is determined by your doctor and suited to your personal needs. It is imperative that you always follow it.
- Remove the peel-off label from the Gammanorm vial and use this to complete the patient diary.

If you use more Gammanorm than you should
The risks of overdosing with Gammanorm are not known. Contact your doctor or NHS 111 if you have taken more Gammanorm than prescribed.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

In rare cases, Gammanorm may cause a fall in blood pressure and a severe hypersensitivity reaction (anaphylactic reaction), even in people who previously tolerated treatment with human normal immunoglobulin.

In case of a suspected allergy or a serious allergic reaction (anaphylactic reaction), you should inform your doctor immediately. The symptoms are, for example, dizziness, heart beat abnormalities, drop in blood pressure, difficulty in breathing and swallowing, tightness of the chest, itching, generalised hives, swelling of the face, tongue or throat, collapse or rash. Any of these conditions requires immediate emergency treatment.

If you get symptoms of a blood clot such as shortness of breath, pain or swelling of an arm or a leg, changes of vision or chest pain, contact your doctor immediately. The occurrence of this side effect is very rare.

If you experience severe headache in combination with symptoms such as neck stiffness, sleepiness, fever, light sensitivity, nausea, vomiting, please contact your doctor immediately. These symptoms can be signs of meningitis. The frequency of this side effect is unknown.

Other side effects are listed below.

Very common: may affect more than 1 in 10 people
Local reactions at the injection site such as swelling, tenderness, pain, redness, hardening, a sensation of heat, itching, bruising, or rashes.

Common may affect up to 1 in 10 people
Headache, dizziness, nausea, vomiting, muscle pain, tiredness.

Uncommon: may affect up to 1 in 100 people
Shivering, feeling hot, feeling cold, feeling unwell, weakness, belly aches, diarrhea, shortness of breath, difficulty breathing or wheezing, hypersensitivity.

Rare: may affect up to 1 in 1,000 people:

Low blood pressure.

Very rare: may affect up to 1 in 10,000 people
Chills, fever, joint pain.

Unknown frequency
Cough, back pain, flushing, rash, hives, itching, flu-like symptoms, swollen face.

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 Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Gammanorm

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

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

Store in a refrigerator (2 °C – 8 °C). Do not freeze. Keep the vial in the outer carton.

Within its shelf-life, the product may be stored below 25 °C for up to 6 months, without being refrigerated again during this period, and must be discarded if not used after this.

After first opening, the product should be used immediately.

Do not use Gammanorm if the solution is cloudy or contains particles.

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.

Never discard used syringes with ordinary household waste.

6. Contents of the pack and other information

What Gammanorm contains
- The active substance is human normal immunoglobulin 165 mg/mL (at least 95% is immunoglobulin G).
- The other ingredients are glycine, sodium chloride, sodium acetate, polysorbate 80 and water for injections.

What Gammanorm looks like and contents of the pack
Gammanorm is a solution for injection and is available as:
6 mL, 10 mL, 12 mL, 20 mL, 24 mL or 48 mL of solution in a vial (Type I glass) - pack size of 1, 10 or 20.
Not all pack sizes may be marketed.

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This leaflet was last revised 10/2023