gammanorm®

Human Normal Immunoglobulin 165 mg/mL, solution for intramuscular injection or subcutaneous infusion

Consumer Medicine Information

gammanorm® contains human normal immunoglobulin G (IgG) (165 mg/mL) with a broad spectrum of antibodies against infectious agents. gammanorm® also contains low levels of IgA (≤ 82.5 microgram/mL).

10 ml vial: AUST R 128703
20 ml vial: AUST R 128705

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about gammanorm®. It does **not** contain complete information about gammanorm®. It does not take the place of talking to your doctor. If you have any concerns about using this product, ask your doctor. Follow your doctor's advice even if it is different from what this leaflet says.

Please read this leaflet carefully and keep it for future reference. However, the information in this leaflet is subject to change. Please check with your doctor whether there is any new information about this product that you should know since you were last treated with this product.

WHAT GAMMANORM IS USED FOR

gammanorm® is prepared from blood obtained from donors. gammanorm® contains proteins known as antibodies which can provide protection against some infections.

gammanorm® is used to treat patients who need replacement of antibodies due to an inherited disease (where antibody levels are low) or in other diseases where a lack of antibodies may cause frequent infections.

Ask your doctor if you have any questions about why gammanorm® has been prescribed for you. Your doctor will have assessed the risks and benefits for you associated with the use of this product.

BEFORE YOUR DOCTOR GIVES YOU GAMMANORM

Special Warning

This product is made from human plasma obtained from donors. 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, and the testing of each donation and pools of plasma for signs of virus/infections. Manufacturers of these products also include steps in the processing of the blood or plasma that can inactivate or remove the viruses. Despite these measures, when medicines prepared from human blood or plasma are administrated, the possibility of passing on infection cannot be totally excluded. This also applies to any unknown or emerging viruses or other types of infections and theoretically to Creutzfeldt-Jacob Disease (CJD) agents.

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.

Vaccines are available against some of these viruses and your doctor will be able to help you decide whether it is worthwhile having any of those vaccines.

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 batch used.

Please discuss the risks and benefits of this product with your doctor.

gammanorm® must not be used if you have a history of allergy to this product or other human immunoglobulin products. Tell your doctor if you have allergies to any other medicines, or if you have ever had an allergic reaction to an injection.

Tell your doctor also if you:

- have previously been advised that you have Immunoglobulin A (IgA) deficiency
- suffer from a blood disorder or blood clotting problem
- are taking or using any other medicines. These include medicines bought from pharmacies, supermarkets and health food stores
- have any other medical conditions
- are pregnant or breast-feeding
- become pregnant during your treatment
- have had any vaccination within the last two weeks or intend to receive one in the next three months

If you want further information, consult your doctor.

HOW TO USE GAMMANORM

gammanorm® should be given as a subcutaneous (under the skin) infusion. Treatment should be started by a doctor experienced with subcutaneous immunoglobulin. The dosage and infusion speed will be determined by your doctor, who will adapt the dose especially for you. If a large volume of product is required, you may receive more than one infusion.

Should your doctor decide that treatment at home is appropriate, your doctor will ensure that you receive training and precise information on using the infusion pump, 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. Always follow your doctor's instructions.

In special cases where gammanorm® cannot be given subcutaneously, it may be administered intramuscularly (into muscle). An intramuscular injection must be given by a doctor or nurse.

Instructions

Always use gammanorm® as instructed by your doctor. Consult your doctor if you are uncertain.

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

The solution should be clear or semi-translucent. 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.
- For withdrawing gammanorm, use a sterile syringe and needle or a transfer device (e.g. Minispike® or Medimop® vial adapter).
- Inject 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.
- Follow the manufacturer's instructions for preparing the pump. Prime the administration tubing to ensure that no air is left in the tubing by filling the tubing/needle with gammanorm®.
- Clean the injection site(s) with antiseptic solution.
- Grasp the skin between two fingers and insert the needle into the subcutaneous tissue.
- **gammanorm® must not be injected into a blood vessel.** To test that no blood vessel has been accidentally hit, gently pull back on the syringe plunger and look to see if any blood is flowing back into the tubing. If you see any blood, remove and discard the needle and tubing. Repeat priming and needle insertion steps using a new needle, tubing and a new infusion site.
- Secure the needle in place by applying sterile gauze or transparent dressing.
- Infuse gammanorm® following the manufacturer's instructions for the pump.
- The infusion site should be changed after 5 - 15 ml.
- Multiple injection sites can be used simultaneously. Injection sites should be at least 5 cm apart.
- Remove the peel-off label from the gammanorm® vial and insert into the patient diary.

Unwanted effects

Along with their intended effects, blood products occasionally cause unwanted effects, some of which are serious. Individuals may also react differently to similar doses of the same medicine. Most minor effects are related to the rate of infusion and disappear when the rate is slowed down or the infusion stopped.

Do not be alarmed by the following list of side effects, you may not experience any of them. You should tell your doctor as soon as possible if you do not feel well while you are being given this medicine.

Common side effects of gammanorm® are local reactions at the injection site such as swelling, tenderness, pain, redness, hardening, a sensation of heat, itching, bruising, or rashes.

Side effects such as low blood pressure and allergic reactions may occasionally occur. In very rare cases, headache, dizziness, nausea, vomiting, moderate pain in the lower back, joint pains, fever, shivering, tiredness and anaphylactic shock (severe hypersensitivity reaction) have been reported.

If you experience any of the above mentioned effects or if you are worried about any other symptoms after administration, consult your doctor or pharmacist.

gammanorm® can interfere with some live vaccines (eg. measles, mumps, rubella and polio), even up to three months later. Advise your doctor if you are to receive other vaccines within three months of receiving gammanorm®.

gammanorm® can also interfere with some blood tests. Advise your doctor if you are to be tested after receiving gammanorm®.

For information on viral safety see **BEFORE YOUR DOCTOR GIVES YOU gammanorm®.**

Overdose (if you take too much)

As gammanorm® is usually given to you under the supervision of your doctor or trained medical professional, it is very unlikely that you will receive an overdose. If you experience several side effects, tell your doctor immediately and your doctor will know what to do.

Although the consequences of an overdose are unknown, it is recommended not to exceed the advised dosage.

HOW TO STORE GAMMANORM

Keep out of reach of children.

Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light.

Do not use after the expiry date stated on the label.

The packaged product may be stored below 25°C for a single period of two months. In this case the product expires at the end of the 2-month period. The product may not be returned to refrigerated storage after storage below 25°C. The date of removal from refrigeration and the new expiry date must be noted on the outer carton.

gammanorm® does not contain any antimicrobial agents. As such, the contents of a vial should be used immediately after opening. Any remaining solution should be discarded by a pharmacy.

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

For environmental and safety reasons, left over or expired medicine should be handed in to a pharmacy for disposal.

Never discard used syringes with ordinary household waste.

Further information

gammanorm® can only be obtained on a doctor's prescription. This leaflet does not contain the complete information about gammanorm®. If you require further information about gammanorm® and your treatment generally, or if you have any questions or are not sure about something in this leaflet, consult your doctor.

PRODUCT DESCRIPTION

What it looks like

gammanorm® is a sterile solution for injection or infusion. The solution should be clear or slightly opalescent and colourless or pale-yellow or light-brown.

Ingredients

Each vial of gammanorm® contains 165 mg/mL of blood proteins of which at least 95% is immunoglobulin. It also contains:

- glycine
- sodium chloride and sodium acetate, equivalent to 2.5 mg of sodium per mL
- polysorbate 80
- water

This medicinal product contains 100 mg sodium per 40 mL. This should be taken into consideration by patients on a controlled sodium diet.

gammanorm® is available as:

- 10 mL of solution in a 20 mL glass vial - pack size of 1, 10 or 20
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SPONSOR

gammanorm® is supplied by:
Octapharma Australia Pty. Ltd.
Jones Bay Wharf
42/26-32 Pirrama Road
Pyrmont NSW 2009
Australia

This leaflet was prepared in December 2012.