Gamunex®

Normal Immunoglobulin (Human), 10% for Intravenous or Subcutaneous Administration

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about GAMUNEX®. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you receiving GAMUNEX® against the benefits they expect it will have for you.

If you have any concerns about receiving this medicine, ask your doctor or pharmacist.

Keep this leaflet.
You may need to read it again.

What GAMUNEX® is used for

GAMUNEX® is used to replace antibodies (used to fight infections) in people with conditions that impair the body's ability to make antibodies. These conditions include:

- Primary Immunodeficiency Diseases.
- Symptomatic Hypogammaglobulinaemia secondary to underlying disease or treatment.

GAMUNEX® is also used to modulate the immune system in people whose immune systems are not working well. These conditions include

- Idiopathic Thrombocytopaenic Purpura (ITP), in patients at high risk of bleeding or prior to surgery to correct the platelet count.
  People with ITP have antibodies that do not work properly and may need treatment with GAMUNEX® to raise blood platelet counts to prevent bleeding or prior to undergoing surgery.
- Guillain Barré Syndrome (GBS).
- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP).
- Kawasaki disease.

This medicine belongs to a group of medicines called immunoglobulins.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.
Your doctor may have prescribed it for another reason.

Before you receive GAMUNEX®

When you must not receive it

You should not receive GAMUNEX® if:

- you have an allergy to immunoglobulin or any of the ingredients listed at the end of this leaflet.
- you have severe immunoglobulin A (IgA) deficiency (which may also cause a severe allergic reaction to this medicine).

Some of the symptoms of an allergic reaction may include:

- shortness of breath,
- wheezing or difficulty breathing,
- swelling of the face, lips, tongue or other parts of the body,
- rash, itching or hives on the skin,
- loss of consciousness.

You should not receive this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.
If it has expired or is damaged, it should be returned to your pharmacist for disposal.

If you are not sure whether this medicine is suitable for you talk to your doctor.

Before you receive it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- renal (kidney) impairment or disease,
- diabetes mellitus,
- volume depletion,
- sepsis (bacterial infection in the blood or tissues),
- paraproteinaemia (abnormal proteins in the blood),
- hypertension (high blood pressure),
- are bed or chair bound,
- atherosclerosis (thickening/hardening of the blood vessel walls),
- heart conditions,
- blood clotting disorders such as thrombosis (clotting in the blood vessels).

Tell your doctor if you are aged over 65 years.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.
It is not known whether GAMUNEX® can affect the developing baby when administered to a pregnant woman or can affect fertility. GAMUNEX® should be given to a pregnant woman only if clearly needed.

Immunoglobulins pass into breast milk and should only be given with caution to breastfeeding mothers.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you receive GAMUNEX®.

Special warning

Because this product is made from human blood, it may carry a risk of transmitting infectious agents, e.g. viruses that can cause disease. The plasma is sourced from US plasma centers licensed by the FDA. The risk that GAMUNEX® will transmit an infectious agent has been reduced by screening blood donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating and/or removing certain viruses. Despite these measures, immunoglobulin products can still potentially transmit disease. There is also the possibility that unknown infectious agents may be present in such products.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor if you are taking an oestrogen medication (such as for birth control). Some medicines and GAMUNEX® may interfere with each other. These include:

- live viral vaccines such as measles, mumps and rubella. GAMUNEX® may interfere with the response to these vaccines. Therefore the use of such vaccines should be deferred until approximately 6 months after GAMUNEX® administration.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while receiving this medicine.

How GAMUNEX® is given

The treating medical professional will give your GAMUNEX® as slow injections (infusions) into the veins. Alternatively, some conditions such as Primary Immunodeficiency Diseases in adult patients can be treated by having patients self-administer GAMUNEX® in their own home, with slow injections under the skin (subcutaneous infusions).

If you are self-administering GAMUNEX® with subcutaneous injections, be sure to closely follow all instructions from your doctor. They may differ from the information contained in this leaflet. You will take GAMUNEX® through infusions given just below the skin (in the subcutaneous tissue). As directed by your physician, one or more injection sites on your body will be selected. The number and location of the injection sites depends on the amount you need to receive. Typically, people use 1 to 4 needles in different locations on your body at one time. You may use up to 8 needles as directed by your doctor. The needles are attached with a tube to the pump. You will need to have infusions once a week.

Instructions for administering GAMUNEX® are shown below. Only use GAMUNEX® by yourself after you have been instructed by your doctor or healthcare professional.

If you do not understand any of the instructions you have been given, ask your doctor, nurse or pharmacist for help.

Steps for Subcutaneous Administration

Before Using GAMUNEX®

- Do not shake the vials.
- Prior to use, allow the solution to come to room temperature (20°C to 25°C). This can take 60 minutes or longer.
- Do not use the vial if:
  - the tape over the carton ends is broken.
  - the solution is cloudy, discolored or contains particles. The solution should be clear to opalescent, and colorless to pale yellow.
  - the band around the vial neck and cap is damaged or missing.
  - the expiration date has passed.
- Sanitize your infusion set-up area by preparing a clean, flat, non-porous surface such as a kitchen counter. Avoid using porous surfaces such as wood. Clean the surface with an alcohol wipe using a circular motion from the center outward.

Step 1:
Wash and dry your hands thoroughly before administering GAMUNEX®

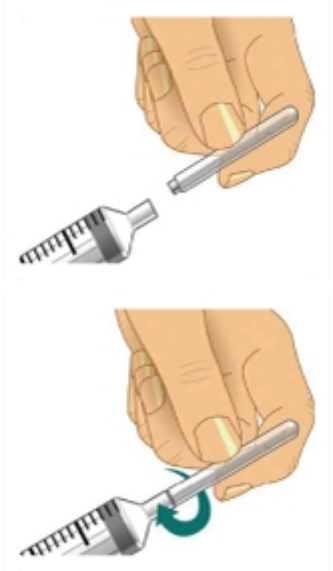
- Your healthcare provider may recommend that you use antibacterial soap or that you wear gloves.

Step 2:
Remove the protective cap and sanitize the rubber stopper

- Remove the protective cap from the vial to expose the central portion of the rubber stopper.
- Wipe the rubber stopper with alcohol and allow to dry.

Step 3:
Use aseptic technique when preparing and administering GAMUNEX®

- Do not allow your fingers or other objects to touch the inner stem of the plunger, the syringe tip, or other areas that will come in contact with your GAMUNEX® solution. This is called aseptic technique and is designed to prevent transmission of germs.
- Using aseptic technique, attach each needle to the syringe tip.



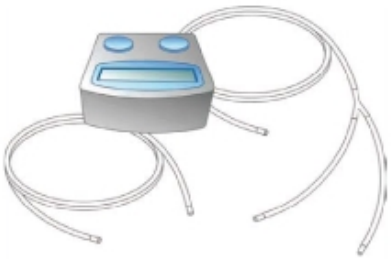
Step 4:
Prepare the syringe and draw GAMUNEX® solution into syringe

- Remove cap from needle.
- Pull the syringe plunger back to the level matching the amount of GAMUNEX® to be withdrawn from the vial.
- Place the GAMUNEX® vial on a clean flat surface and insert the needle into the center of the vial stopper.
- Inject air into the vial. The amount of air should match the amount of GAMUNEX® to be withdrawn.
- Turn the vial upside down and withdraw the correct amount of GAMUNEX®. If multiple vials are required to achieve the correct dose, repeat Step 4.

Step 5:
Fill the pump reservoir and prepare the infusion pump

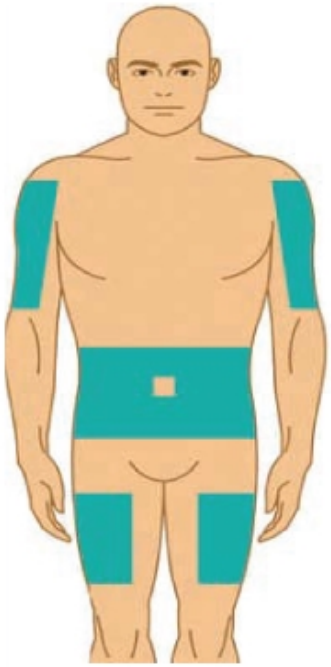
- Follow the pump manufacturer's instructions for filling the pump reservoir and preparing the infusion pump, administration tubing and Y-site connection tubing, if needed.
- Be sure to prime the administration tubing to ensure that no air is left in the tubing or needle by filling the tubing/needle with GAMUNEX®. To prime, hold the syringe in one hand and the administration tubing's capped needle in the other. Gently squeeze on the plunger until you see a drop of GAMUNEX® exit from the needle.

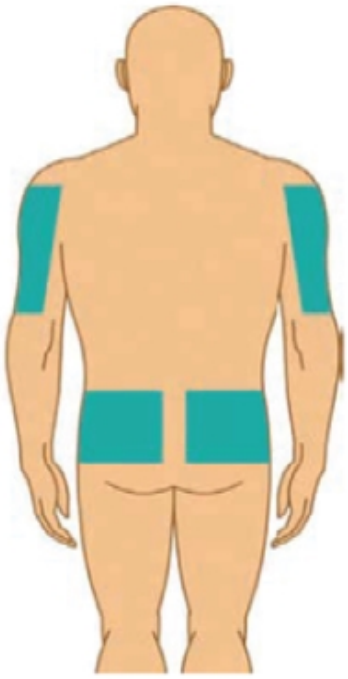
Example Equipment



Step 6:
Select the number and location of infusion sites

- Select one or more infusion sites as directed by your healthcare provider.
- The number and location of injection sites depends on the volume of the total dose.



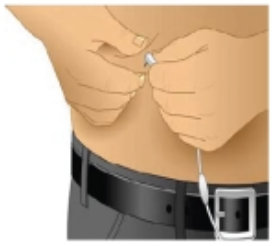


Step 7:
Prepare the infusion site

- Cleanse the infusion site(s) with antiseptic solution using a circular motion working from the center of the site and moving to the outside.
- Sites should be clean, dry, and at least 5 centimetres apart.

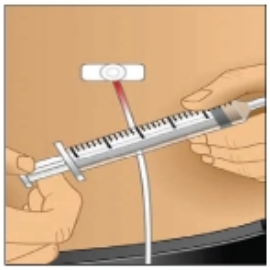
Step 8
Insert the needle

- Grasp the skin between two fingers and insert the needle into the subcutaneous tissue.

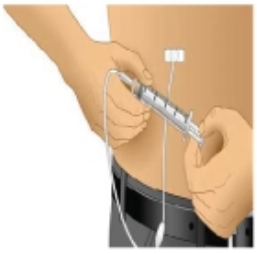


Step 9:
Do not inject GAMUNEX® into a blood vessel

- After inserting each needle into tissue (and before your infusion), make sure that a blood vessel has not been accidentally entered. To do this, attach a sterile syringe to the end of the primed administration tubing. Pull back on the syringe plunger and watch for any blood flowing back into administration tubing.
- If you see any blood, remove and discard the needle and administration tubing.



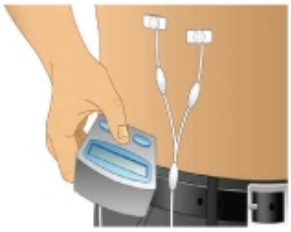
- Repeat priming and needle insertion steps using a new needle, administration tubing and a new infusion site.
- Secure the needle in place by applying sterile gauze or transparent dressing over the site.



Step 10:
Repeat for other sites, as needed

- If using multiple, simultaneous infusion sites, use Y-site connection tubing and secure to the administration tubing.

Step 11:
Infuse GAMUNEX® following the pump manufacturer's instructions for the infusion pump



Step 12:
After infusion, turn off pump and dispose of used supplies

- Follow manufacturer's instructions to turn off pump.
- Undo and discard any dressing or tape.
- Gently remove the inserted needle(s) or catheter(s).
- Discard any unused solution in an appropriate waste container as instructed.
- Discard any used administration equipment in an appropriate waste container.
- Store your supplies in a safe place.
- Follow manufacturer's instructions to care for the infusion pump.

Step 13:
Record each infusion

- Remove the peel-off label with the product lot number and expiration date from the GAMUNEX® vial and use this to complete the patient record.
- Remember to bring your journal with you when you visit your physician or healthcare provider.

Be sure to tell your doctor about any problems you have doing your infusions. Your doctor may ask to see your journal, so be sure to take it with you each time you visit the doctor's office.

How much GAMUNEX® is given

Your doctor will calculate the dose of GAMUNEX® that you are to receive. Your dose will depend on factors such as your condition, body weight and response to the medicine.

If you miss a dose

If you miss a dose talk to your doctor and arrange another visit as soon as possible.

If you are not sure what to do, ask your doctor or pharmacist.

If you receive too much (overdose)

Overdose may lead to fluid overload and increased viscosity ("thickness") of the blood.

Immediately telephone your doctor or the Poisons Information Centre (telephone13 11 26) for advice, or go to Accident and Emergency at the nearest hospital if you think that you may have self-administered too much GAMUNEX®. Do this even if there are no signs of discomfort or poisoning.
You may need urgent medical attention.

While you are receiving GAMUNEX®

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are receiving GAMUNEX® therapy.

Tell any other doctors, dentists, and pharmacists who treat you that you are being treated with this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are being treated with this medicine.
It may affect other medicines used during surgery.

If you become pregnant while receiving this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are receiving this medicine.
It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.
Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

If you are self-administering GAMUNEX®, do not stop using it or change the dosage without checking with your doctor.

Things to be careful of

You should immediately tell your doctor if you experience any of the following during treatment with GAMUNEX®:

- decreased urine output,
- sudden weight gain,
- fluid retention/oedema,
- shortness of breath.

Side Effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being treated with GAMUNEX®.

This medicine helps most people with the conditions listed at the start of this leaflet, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Some side effects are more common with the first dose of **GAMUNEX®**.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- chills,
- headache,
- dizziness,
- mild fever,
- nausea,
- vomiting,
- diarrhoea,
- sore throat, cough or nasal congestion,
- pain or reaction at the injection site.

The above side effects are usually mild and short-lived

Tell your doctor as soon as possible if you notice any of the following:

- mild skin reaction such as rash, itching,
- tiredness or loss of strength/energy,
- pain in the abdomen,
- joint pain,
- mild back or shoulder pain,
- infections.

The above list includes more serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- severe allergic reaction (with symptoms such as shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, loss of consciousness),
- difficulty breathing,
- severe headache, stiff neck, drowsiness, fever, sensitivity to light, painful eye movements, nausea and vomiting (these may be signs of aseptic meningitis),
- severe tiredness or generalised weakness, lightheadedness, dark urine, jaundice (yellow skin and eyes) and/or pale complexion (these may be signs of haemolytic anaemia),

- fluid retention/oedema (swelling) or decreased urine output (these may be signs or impaired kidney function),
- chest pain or discomfort that worsens on deep breathing, unexplained rapid pulse, unexplained shortness of breath, numbness or weakness on one side of the body, or swelling, pain, or warmth and redness of the arm or leg (these could be signs of a blood clot).

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor or nurse if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some side effects (for example, low blood pressure, impairment of renal function with elevation of serum creatinine) can only be found when your doctor does tests from time to time to check your progress.

After receiving GAMUNEX®

If you need to keep your GAMUNEX® at home follow these instructions for storage and disposal.

Storage

Store GAMUNEX® in the refrigerator (2ºC to 8ºC). Do not freeze.

Do not use after the expiry date.

Tape over carton ends must be unbroken.

Do not use if the band around vial neck and cap is damaged or missing.

Do not use if turbid.

Solution that has been frozen should not be used.

Once removed from the fridge GAMUNEX® can be stored below 25ºC for use within 6 months.

Discard unused portion. Do not store after entry into vial.

Keep it where children cannot reach it.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

GAMUNEX® is a clear solution which is colourless to pale yellow. It is available in glass vials.

Ingredients

In each vial of GAMUNEX® is a sterile solution containing 10% blood proteins of which at least 98% is immunoglobulin.

It also contains:

- water for injections
- glycine.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Australian Registration Numbers

10 mL AUST R 116689

25 mL AUST R 117237

50 mL AUST R 117238

100 mL AUST R 117239

200 mL AUST R 117240

400 mL AUST R 371434

Not all pack sizes may be marketed.

Sponsor

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Australia

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