

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'  
REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only.

## **Gamunex<sup>®</sup>-C** Solution for infusion

Immunoglobulins, Normal Human 0.1 g/mL (10%)

For a list of inactive and allergenic ingredients in the preparation, please see section 6 "Further Information". **Read the leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine.

If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

### **Important information about the medicine**

Gamunex-C is intended for administration by subcutaneous infusion (into the subcutaneous tissue). Do not inject Gamunex-C directly into a blood vessel or muscle. IV administration (directly into a blood vessel) of Gamunex-C will only be performed by the medical staff (not by the patient) in a clinic or hospital.

#### **Warning: Thrombosis, renal failure and acute renal insufficiency**

- Thrombosis may occur with the use of immunoglobulins, including Gamunex-C. Risk factors for this can include: older age, prolonged immobility, conditions that cause hypercoagulability of the blood, history of venous or arterial thrombosis, use of estrogen, use of central vascular catheter(s), hyperviscosity of the blood, and cardiovascular risk factors.
- Renal failure, acute renal insufficiency, impairment of renal function and death may occur when using immunoglobulin products for intravenous use in patients at risk for this.
- Renal failure and acute renal insufficiency may occur more frequently in patients receiving intravenous immunoglobulin products that contain sucrose. Gamunex-C does not contain sucrose.

### **1. WHAT IS THE MEDICINE INTENDED FOR?**

- Gamunex-C is used as an alternative treatment in primary immunodeficiency (PI) situations in which the body's ability to produce antibodies is impaired, such as:
  - Congenital agammaglobulinemia
  - Common variable immunodeficiency
  - Immunodeficiency diseases that are linked to the X chromosome with hyper IgM (X-linked immunodeficiency with hyper-IgM)
  - Wiskott-Aldrich syndrome
  - Severe combined immunodeficiencies

Additional indications for Gamunex-C (intravenous administration only):

- Gamunex-C is also indicated for the treatment of idiopathic thrombocytopenia purpura (ITP) to increase the platelet count in order to prevent bleeding or allow the patient to undergo surgery.
- Gamunex-C is intended for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP).

**Therapeutic group:** Human immunoglobulins.

## 2. BEFORE USING THE MEDICINE

### **Do not use the medicine if:**

- You are sensitive (allergic) to the active substance or to any of the additional ingredients contained in the medicine.
- There is a history of a hypersensitivity reaction (anaphylaxis) or a severe systemic reaction to medicines containing immunoglobulin (human).
- You have immunoglobulin A (IgA) deficiency with antibodies against immunoglobulin A (IgA).
- You have a history of hypersensitivity to immunoglobulin A (IgA).

### **Special warnings regarding use of the medicine**

- Serious hypersensitivity reactions may occur with Gamunex-C.
- An increase in the amount of proteins in the blood (hyperproteinemia), an increased viscosity of the serum and a decrease in the concentration of sodium in the blood are possible in patients receiving treatment with intravenous immunoglobulins, including Gamunex-C.
- Thrombosis may occur in the absence of known risk factors.
- Aseptic meningitis may occur during treatment with intravenous immunoglobulins, including Gamunex-C.
- Breakdown of red blood cells (hemolysis) may occur during treatment with intravenous immunoglobulins.
- Acute lung injury may occur during treatment with intravenous immunoglobulins, including Gamunex-C.
- Because Gamunex-C is produced from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the agent that is responsible for Creutzfeldt-Jakob disease (CJD). No cases of transmission of any viral disease or CJD via the Gamunex-C preparation have been identified.

### **Before treatment with Gamunex-C, tell the doctor if:**

- You are pregnant, planning a pregnancy or are breastfeeding.
- You are sensitive to any food or medicine.
- You are receiving immunoglobulin products, such as Gamunex-C, because certain vaccine components (those which contain a live virus component) may be less effective for you. The antibodies in Gamunex-C may prevent the activity of the vaccine. If you are due to be vaccinated, report to the doctor or nurse that you are receiving Gamunex-C.

### **Tests and follow-up**

- During the treatment period with Gamunex-C, you may be referred for medical tests depending on your health condition.
- Before the start of the treatment and during it, you will be periodically referred for urine and kidney function tests.

#### **Drug interactions:**

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:**

Certain vaccines (containing live virus components) such as measles, mumps, rubella and chickenpox vaccine.

#### **Pregnancy and breastfeeding**

If you are pregnant or planning to become pregnant or are breastfeeding, consult the doctor.

### **3. HOW SHOULD YOU USE THE MEDICINE?**

- Always use the preparation according to the doctor's instructions.
- Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.
- The dosage and treatment regimen will be determined by the doctor only.
- Do not self-inject Gamunex-C unless you have received guidance and training by the doctor or the nurse treating you.

**Do not exceed the recommended dose.**

#### **Instructions for use:**

Self-infusion of Gamunex-C will be administered under the skin (subcutaneous tissue) once a week.

According to your doctor's instructions, one or more injection sites on your body will be selected. The number and location of injection sites will be determined according to the amount you need to receive. Typically, patients may use 1 to 4 needles in different locations on the body, in one injection. Up to 8 needles may be used, as per your doctor's instructions. Make sure that the distance between one infusion area and another is at least 5 cm.

The needles are connected to the pump through a tube.

Before use, allow the solution to reach room temperature (20°C-25°C) – this may take an hour or more.

Do not shake the vials.

#### **Do not use the vial if:**

- The solution is cloudy or discolored or contains particles. The solution is supposed to be clear to opalescent, colorless to light yellow.
- The protective seal or plastic shrink band around the cap is missing, or there is any evidence of damage to the product. Report to the doctor immediately.
- The expiry date has passed.

Below are step-by-step instructions that will help you remember how to use Gamunex-C. Refer to the doctor or nurse regarding any instruction that is not clear to you.

**Steps for injection:**

Prepare the preparation area for infusion by setting up a clean, flat and non-porous surface such as a marble kitchen counter, and disinfect it. 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 injecting Gamunex-C**

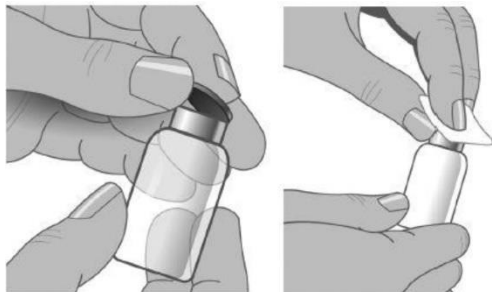
- The doctor may recommend that you use anti-bacterial soap or gloves (see Fig. No. 1).



**Step 2:**

**Removing the protective cap and sanitizing the stopper**

- Remove the protective cap from the vial to expose the central portion of the stopper.
- Wipe the stopper with alcohol and allow it to dry (see Fig. No. 2).

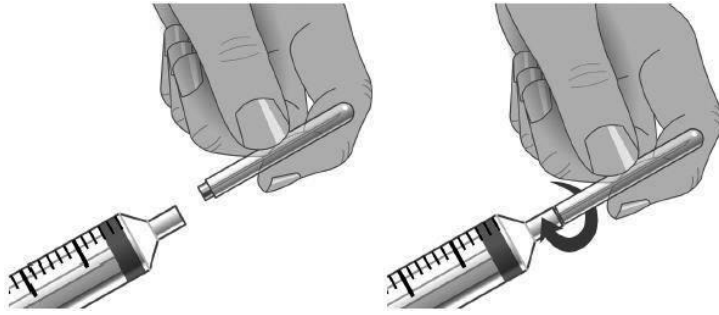


**Step 3:**

**Use of aseptic technique when preparing and administering Gamunex-C**

- Avoid contact of the fingers or any other object with the inner stem of the plunger, syringe tip, or with any other area that will come in contact with your Gamunex-C solution. This is aseptic technique and is designed to prevent the transmission of bacteria.

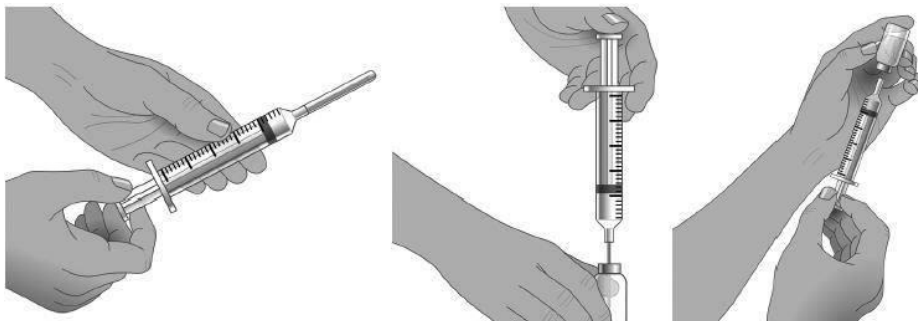
- Attach each needle to the syringe tip while taking care to use aseptic technique (see Fig. No. 3).



#### **Step 4:**

##### **Preparing the syringe and drawing Gamunex-C solution into the syringe**

- Remove the cap from the needle.
- Pull the syringe plunger back to the level matching the amount of Gamunex-C solution to be withdrawn from the vial.
- Place the Gamunex-C vial on a flat and clean surface and insert the needle into the center of the vial cap.
- Inject air into the vial. The amount of air should match the amount of Gamunex-C solution to be withdrawn.
- Turn the vial upside down and withdraw the correct amount of Gamunex-C solution. If multiple vials are required to reach the correct dosage, repeat Step 4 (see Fig. No. 4).

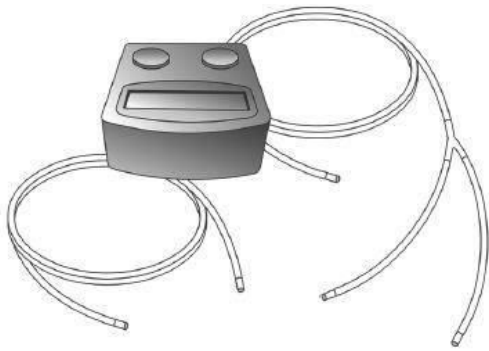


#### **Step 5:**

##### **Filling the pump reservoir and preparing the infusion pump**

- Follow the instructions of the pump manufacturer for filling the pump reservoir and preparing the infusion pump, infusion tubing and Y-site connection tubing, if needed.
- Be sure to prime the tubing to ensure that no air is left in the tubing or needle by filling the tubing/needle with Gamunex-C solution. To prime the tubing/needle for use, hold the syringe in one hand and the needle attached to the infusion tubing in the other. Gently press on the pump plunger until you see a drop of Gamunex-C exit from the needle (see Fig. No. 5).

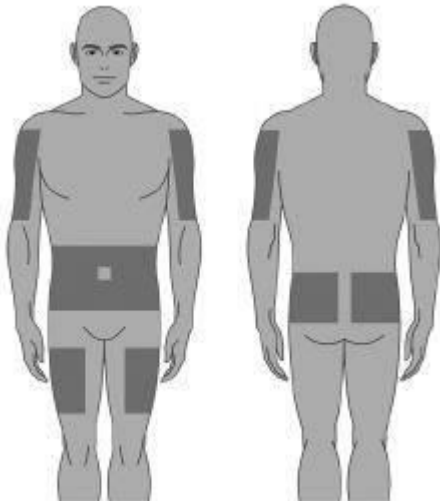
## Device example



### **Step 6:**

#### **Selecting the number and locations of infusion sites**

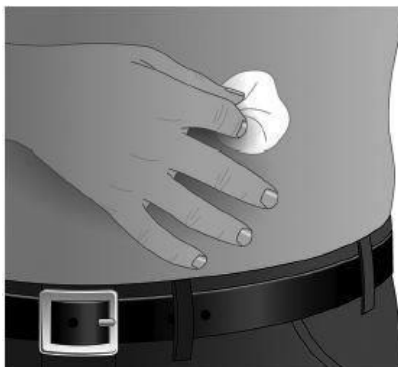
- Select one or more infusion sites, according to your attending doctor's instructions.
- The number and location of infusion sites depends on the volume of the total dose (see Fig. No. 6).



### **Step 7:**

#### **Preparing the infusion site**

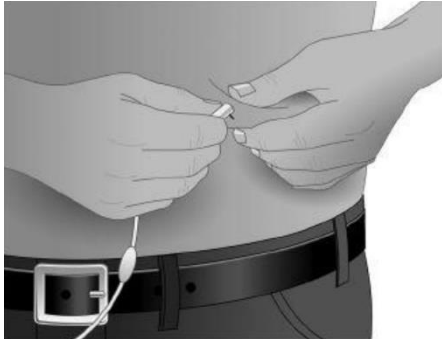
- Clean the infusion site/sites with antiseptic solution using a circular motion, working from the center outward.
- The infusion sites must be clean, dry and at least 5 cm apart (see Fig. No. 7).



**Step 8:**

**Inserting the needle**

- Grasp the skin between two fingers and insert the needle into the subcutaneous tissue (see Fig. No. 8).



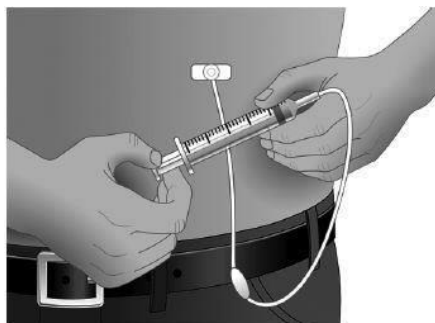
**Step 9:**

**Do not inject Gamunex-C into a blood vessel**

- After inserting the needle into the tissue (and before your infusion), make sure that the needle did not enter a blood vessel. To do this, attach a sterile syringe to the end of the infusion tubing filled with solution, pull back on the syringe plunger and check whether any blood flowed back into the infusion tubing.
- If blood flowed back in, remove and discard the needle and infusion tubing (see Fig. No. 9).



- Repeat the initial preparations steps upon insertion of a new needle, new infusion tubing and a new infusion site.
- Secure the needle in place by applying sterile gauze or sterile transparent dressing over the infusion site (see Fig. No. 10).



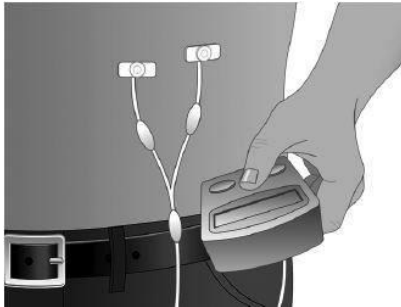
**Step 10:**

**Repeat the procedure for other infusion sites, as needed.**

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

**Step 11:**

**Infusion of Gamunex-C must be done according to instructions for use of the pump manufacturer (see Fig. No. 11).**



**Step 12:**

**After the infusion, turn off the pump and dispose of the used supplies in the appropriate receptacle**

- Turn off the pump according to the manufacturer's instructions.
- Gently remove all bandages or tape.
- Gently remove used needles or catheters.
- Discard all of the remaining solution in an appropriate waste container as per the instructions.
- Discard any injection equipment in an appropriate receptacle.
- Store the supplies in a safe place.
- Follow the manufacturer's instructions for care of the infusion pump.

**Step 13:**

**Record each injection**

- Remove the sticker with the product lot number from the Gamunex-C vial and record it when filling out the patient record.
- Remember to bring the follow-up log when you visit your attending doctor.

Be sure to notify your doctor about any problem encountered during your infusions. Your doctor may want to look at your patient record. Therefore, you should remember to bring it with you to each visit at the doctor's clinic.

**If you accidentally took a higher dosage**

If you took an overdose, or if a child has accidentally swallowed the medicine, immediately proceed to a hospital emergency room and bring the package of the medicine with you.

**If you forgot to take the medicine**

If you forgot to take this medicine at the designated time, do not take a double dose. Take the next dose at the usual time and consult the doctor.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine



without consulting the doctor.

**Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.**

**If you have further questions regarding use of the medicine, consult the doctor or pharmacist.**

#### **4. SIDE EFFECTS**

As with any medicine, use of Gamunex-C may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

**Refer to a doctor or emergency room immediately if some of the following symptoms appear** that may indicate a serious allergic reaction:

- Hives
- Breathing difficulties
- Wheezing
- Dizziness or fainting

**Refer to a doctor immediately if you have any of the following symptoms**, which may indicate a rare and severe problem:

- Decreased urination, sudden weight gain, fluid retention/swelling of the legs and/or shortness of breath; these symptoms could indicate a severe kidney problem called renal insufficiency.
- Pain and/or swelling in the leg or arm accompanied by warmth in the affected area, color change of the arm or leg, unexplained shortness of breath, chest pain or discomfort that worsen upon deep breathing, unexplainable rapid heartbeat, numbness or weakness on one side of the body. These symptoms could indicate a blood clot in your body (thrombosis – blood clot embolism). Report symptoms of thrombosis to a doctor immediately.
- Severe headache, neck stiffness, fatigue, fever, sensitivity to light, painful eye movements, nausea and vomiting. These symptoms could indicate aseptic meningitis.
- Increased heart rate, fatigue, yellow skin or eyes and dark-colored urine. These symptoms could indicate a blood problem called hemolytic anemia.
- Chest pains, breathing difficulties, blue lips or extremities and fever. These symptoms could indicate an acute lung injury called TRALI – transfusion-related acute lung injury.
- Body temperature over 37.8°C. This symptom could indicate an infection.

It is important that you report to your doctor any side effect that concerns you.

**The most common side effects in the subcutaneous administration of Gamunex-C are:**

- Redness, swelling and itching at the injection site
- Fatigue
- Headache

- Upper respiratory tract infection
- Pain (including pain in the joints, hands and legs)
- Diarrhea
- Nausea
- Sinusitis (chronic inflammation of the sinuses)
- Bronchitis
- Depression
- Allergic dermatitis (skin inflammation)
- Erythema
- Migraine
- Muscle pain
- Viral infection
- Fever

**If a side effect occurs, if any of the side effects worsen or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.**

#### **Reporting side effects:**

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

In addition, you can report to Padagis via the following address: [Padagis.co.il](http://Padagis.co.il)

### **5. HOW SHOULD THE MEDICINE BE STORED?**

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the carton and the label of the vial.
- Store refrigerated (2°C-8°C). Do not freeze!  
Gamunex-C can be stored below 25°C, for up to 6 months, but you must use the preparation within this period of time; otherwise, it must be discarded. **If stored outside the refrigerator, do not return to the refrigerator.**
- Store in outer packaging to protect from light.

### **6. FURTHER INFORMATION**

- In addition to the active ingredient, the medicine also contains: glycine, water for injection.
- What the medicine looks like and the contents of the package:  
Gamunex-C is provided in disposable vials that contain a clear to opalescent, colorless to light yellow solution.
- Package size: 10, 25, 50, 100, 200 mL. Not all package sizes may be marketed.
- Registration holder: Padagis Israel Agencies, 1 Rafeket St., Shoham.
- Manufacturer: Grifols Therapeutics LLC, North Carolina, United States.

- Revised in September 2023 according to MOH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 132-95-31058

Gamunex-C is a registered trademark of Grifols Therapeutics LLC

04/09/2023