

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

The medicine is dispensed with a doctor's prescription only

Gamunex-C

Solution for infusion

Immunoglobulin Normal Human 0.1 g/ml (10%).

Read this 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 ON THE MEDICINE

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

1. WHAT IS THE MEDICINE INTENDED FOR?

Gamunex-C is an immunoglobulin that is used to treat cases of primary immunodeficiency in which the body's ability to produce antibodies is impaired.

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

- Thrombocytopenic purpura (a sharp decline in the number of platelets).
- Chronic inflammatory demyelinating polyneuropathy (CIDP) – an acquired neurological disease of the peripheral nervous system.

Therapeutic group: Human immunoglobulins.

2. BEFORE USING THE MEDICINE

- Do not use the medicine if:**
 - You are sensitive (allergic) to the active ingredient or to any of the other components of the medicine.
 - You know that you develop severe allergic reactions or a severe reaction to immunoglobulin (human).
 - You have had a severe reaction in the past to other medicines containing immunoglobulin. You must inform your doctor about this.
 - You are immunoglobulin A (IgA)-deficient, with antibodies against IgA and a history of hypersensitivity.

Special warnings regarding use of the medicine

- When using immunoglobulin products, including Gamunex-C, thrombosis (a blood clot) may form. Risk factors can include: advanced age, prolonged lack of movement, conditions that cause hypercoagulation, history of venous or arterial thrombosis, use of estrogens, use of catheter(s) in central blood vessels, hyperviscosity of the blood, cardiac risk factors. Thrombosis may also occur in the absence of risk factors.
- Renal insufficiency, renal failure and death may occur when using immunoglobulin products intravenously in patients with the relevant risk factors. Risk factors for renal insufficiency are: patients with existing renal insufficiency, diabetes, age over 65, decreased blood volume, sepsis, disturbances in blood proteins and patients receiving medicines that damage the kidney. Renal insufficiency and failure occur more often in patients receiving intravenous immunoglobulins in preparations containing sucrose. Gamunex-C does not contain sucrose.
- Increased concentration of proteins in the blood (hyperproteinemia), increased viscosity of the serum and decreased concentration of sodium in the blood may occur in patients receiving intravenous treatment with immunoglobulins, including Gamunex-C.
- Because Gamunex-C is made 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 Gamunex-C have been identified.

Inform the doctor if one or more of the above-mentioned risk factors apply to you.

Before treatment with Gamunex-C, inform the doctor if:

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

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist.

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 according to the doctor's instructions.
- Check with the doctor or pharmacist if you are uncertain.
- 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:

Gamunex-C is provided in disposable vials. Do not freeze them. Keep them refrigerated. If necessary, Gamunex-C can be stored at room temperature for up to 6 months, but the medicine must be used within this period of time, otherwise, it must be discarded. **If stored outside the refrigerator do not return to the refrigerator.** Do not shake the vials.

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

Do not use the vial if:

- The solution is cloudy or has an abnormal color or contains particles. The solution is supposed to be clear to opalescent, colorless or 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.
- Gamunex-C is injected under the skin (in the

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 use 1 to 4 needles in different locations on the body at one time. Up to 8 needles may be used, as per your doctor's instructions. The needles are connected to the pump through a tube.
- Gamunex-C can be self-injected only after you have received guidance and training by the doctor or nurse treating you.
- Below are the instructions for the steps of infusion that will help you remember how to use Gamunex-C. Refer to the doctor or nurse regarding any instruction that is not clear.

Steps for administration:

Prepare the injection area – 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 administering 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 which prevents transmission of bacteria and contamination when preparing and administering Gamunex-C: Avoid contact of the fingers or any other object with the inner stem of the plunger or with the syringe tip, or with any other area that will come in contact with the Gamunex-C solution. 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 clean and flat 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).

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 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 the 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 priming 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 used supplies in the appropriate receptacle: Turn off the pump according to the manufacturer's instructions. Gently undo any dressing, tape, needles or catheters that were penetrated and discard any injection equipment in an appropriate receptacle. Discard all of the unused solution in an appropriate waste container as per the instructions.

Store the supplies in a safe place. Follow the manufacturer's instructions for care of the infusion pump.

Step 13:

Record each infusion: Remove the peel-off label with the product lot number from the Gamunex-C vial and record it when filling out the patient record.

Tests and follow-up

During the course of treatment with Gamunex-C, you may be referred for medical tests in accordance with your health condition. Be sure to notify your doctor about any problem encountered during your injections. Your doctor may want to look at your 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. **Do not induce vomiting** without explicit instruction from the doctor!

If you forgot to take the medicine

If you forgot to take this medicine at the required time, refer to the doctor.

Do not take a double dose.

How can you contribute to the success of the treatment?

Adhere to the treatment regimen 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 a 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.

The most common side effects when subcutaneously injecting Gamunex-C are:

- Redness, swelling and itching at the infusion site
- Fatigue
- Headache
- Upper respiratory tract infection
- Pain (including pain in the joints, hands and legs)
- Diarrhea
- Nausea
- Sinusitis
- Bronchitis
- Depression
- Dermatitis
- Migraine
- Muscle pain (myalgia)
- Viral infection
- Fever

If you experience one or more of the mentioned symptoms, inform your doctor immediately.

Refer to a doctor or hospital immediately if any of the following symptoms develop (that may indicate a serious allergic reaction):

- Hives
- Breathing difficulties
- Wheezing
- Dizziness or fainting

Refer to a doctor immediately if any of the following symptoms develop (that 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, dark-colored urine; these symptoms could indicate a blood problem (hemolytic anemia).
- Chest pain, trouble breathing, blue lips or extremities, fever; these symptoms could indicate an acute lung injury whose treatment involves transfusion (TRALI – transfusion-related acute lung injury).
- Body temperature over 37.8°C could indicate an infection.

It is important that you report any side effect that worries you to your doctor. You can request the full information available to health experts from your doctor.

If a side effect occurs, if any of the side effects worsen or if you experience side effects not mentioned in this leaflet, consult 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) that directs you to the online form for reporting side effects, or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@mol.gov.il>

In addition, you can report to Perrigo via the following address: www.perrigo-pharma.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

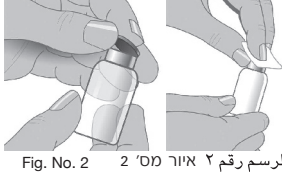
- Avoid poisoning! This medicine, and any other medicine must be kept in a safe place out of the sight and reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the carton and the label of the vial. The expiry date refers to the last day of that month.
- Store refrigerated (2°C-8°C). Do not freeze!
- If necessary, Gamunex-C can be stored at room temperature (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.**
- Even when stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the preparation! In any case of doubt, consult the pharmacist who dispensed the medicine to you.

6. FURTHER INFORMATION

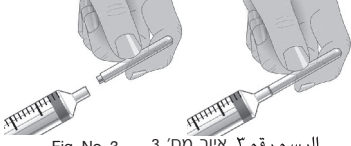
- In addition to the active ingredient, the medicine also contains: Glycine, water for injection.
- What the medicine looks like and the contents of the pack: Gamunex-C is provided in disposable vials that contain a clear to opalescent, colorless or light yellow solution.
- Registration holder: Perrigo Israel Agencies Ltd., 1 Rakefet St., Shoham.
- Manufacturer: Grifols Therapeutics LLC., North Carolina, USA.
- This leaflet was checked and approved by the Ministry of Health in May 2014.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 13295.31058



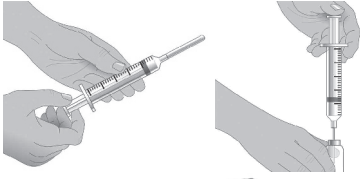
الرسم رقم ١ איור מס' 1 Fig. No. 1



الرسم رقم ٢ איור מס' 2 Fig. No. 2



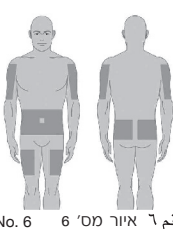
الرسم رقم ٣ איור מס' 3 Fig. No. 3



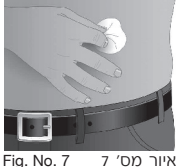
الرسم رقم ٤ איור מס' 4 Fig. No. 4



الرسم رقم ٥ איור מס' 5 Fig. No. 5



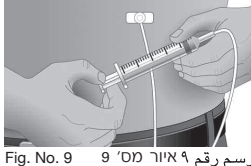
الرسم رقم ٦ איור מס' 6 Fig. No. 6



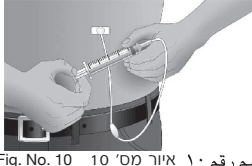
الرسم رقم ٧ איור מס' 7 Fig. No. 7



الرسم رقم ٨ איור מס' 8 Fig. No. 8



الرسم رقم ٩ איור מס' 9 Fig. No. 9



الرسم رقم ١٠ איור מס' 10 Fig. No. 10



الرسم رقم ١١ איור מס' 11 Fig. No. 11