# הודעה על החמרה (מידע בטיחות) בעלון לצרכן

(מעודכן 3102.50)

**תאריך** 2.04.2014

**שם תכשיר באנגלית ומספר הרישום**

Gamunex C Reg. No. 132-95-31058-00

**שם בעל הרישום** _ פריגו ישראל סוכנויות בע"מ, רח' לח"י 29 בני ברק 51200 _

טופס זה מיועד לפרוט ההחמרות בלבד !

| ההחמרות המבוקשות | | |
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| **פרק בעלון** | **טקסט נוכחי** | **טקסט חדש** |
| **תופעות לוואי:** | בנוסף לפעילות הרצויה של התרופה, בזמן השימוש בה עלולות להופיע תופעות לוואי.<br>תופעות הלוואי השכיחות ביותר בהזרקה תת-עורית של גאמונקס-סי הן:<br>אודם, נפיחות וגרד במקום ההזרקה, כאב ראש, תשישות, כאב (לרבות כאב בגב, במפרקים, בידיים וברגליים), חום.<br>אם יופיע אצלך אחד או יותר מהתסמינים המוזכרים, עליך לדווח על כך לרופא שלך באופן מיידי.<br>התסמינים הבאים עלולים להעיד על בעיה נדירה וחמורה: הפחתה במתן שתן, עליה פתאומית במשקל, אצירת נוזלים/נפיחות ברגליים, קוצר נשימה; תסמינים אלה עלולים להעיד על אי ספיקה בכליות.<br>כאב חד בחזה, | כמו בכל תרופה, השימוש בגמונקס סי עלול לגרום לתופעות לוואי בחלק מהמשתמשים. אל תיבהל למקרא רשימת תופעות הלוואי. ייתכן ולא תסבול מאף אחת מהן.<br>**תופעות הלוואי השכיחות ביותר בהזרקה תת-עורית של גאמונקס-סי הן:**<br>• אודם, נפיחות וגרד במקום ההזרקה<br>• כאב ראש<br>• תשישות<br>• כאב (לרבות כאב בגב, במפרקים, בידיים וברגליים)<br>• חום<br>אם יופיע אצלך אחד או יותר מהתסמינים המוזכרים, עליך לדווח על כך לרופא שלך באופן מיידי. |

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| | קוצר נשימה, כאב ברגליים ונפיחות ברגליים/בכפות הרגליים; תסמינים אלה עלולים להעיד על הימצאות קריש דם בגופך (תסחיף קריש דם).<br>כאב ראש קשה, קשיון צוואר, תשישות, חום, רגישות לאור, כאב בעת תנועת עיניים, בחילות והקאות; תסמינים אלה עלולים להעיד על דלקת קרום המוח.<br>קצב לב מוגבר, תשישות, עור צהוב או עיניים צהובות, שתן כהה; תסמינים אלה עלולים להעיד על בעיית דם (אנמיה המוליטית).<br>כאבים בחזה, קשיי נשימה, כיחלון בשפתיים או בגפיים, חום; תסמינים אלה עלולים להעיד על פגיעה ריאתית חריפה שהטיפול בה כרוך בעירוי (TRALI - transfusion related acute lung injury).<br>חום גוף מעל 37.8°C עלול להעיד על זיהום.<br>אם יופיעו אצלך תסמינים של סרפדת, קשיי נשימה, צפצופים, סחרחורת או עילפון, עליך לדווח על כך לרופא שלך באופן מיידי או לפנות לחדר מיון. תסמינים אלה עלולים להעיד על תגובה אלרגית קשה.<br>חשוב לדווח לרופא שלך על כל תופעת לוואי המדאיגה אותך. תוכל/י לבקש מהרופא שלך את המידע המלא שזמין למומחי הבריאות.<br>בכל מקרה שבו הינך מרגיש/ה תופעות לוואי שלא צויינו בעלון זה, או אם חל שינוי בהרגשתך הכללית עליך להתייעץ עם הרופא מיד. | **יש לפנות מיד לרופא או לבית החולים אם מופיעים חלק מהתסמינים הבאים** (שעלולים להעיד על תגובה אלרגית קשה)**:**<br>• סרפדת,<br>• קשיי נשימה,<br>• צפצופים<br>• סחרחורת או עילפון<br><br>**יש לפנות מיד לרופא אם מופיעים חלק מהתסמינים הבאים** (שעלולים להעיד על בעיה נדירה וחמורה)**:**<br>• הפחתה במתן שתן, עליה פתאומית במשקל, אצירת נוזלים/נפיחות ברגליים, קוצר נשימה; תסמינים אלה עלולים להעיד על אי ספיקה בכליות.<br>• ~~כאב חד בחזה, קוצר נשימה, כאב ברגליים ונפיחות ברגליים/בכפות הרגליים~~; כאב ו/או נפיחות ברגליים או ידיים שמלווה בחום באזור הפגוע , שינוי צבע של יד או רגל, קוצר נשימה לא מוסבר, כאבים בחזה או אי נוחות שמחמירים בנשימה עמוקה, הגברת הדופק בלתי מוסברת, חוסר תחושה או חולשה בצד אחד של הגוף. תסמינים אלה עלולים להעיד על הימצאות קריש דם בגופך (תסחיף קריש דם).<br>• כאב ראש קשה, קשיון צוואר, תשישות, חום, רגישות לאור, כאב בעת תנועת עיניים, בחילות והקאות; תסמינים אלה עלולים להעיד על דלקת קרום המוח.<br>• קצב לב מוגבר, |

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| | | תשישות, עור צהוב או עיניים צהובות, שתן כהה; תסמינים אלה עלולים להעיד על בעיית דם (אנמיה המוליטית).<br>• כאבים בחזה, קשיי נשימה, כיחלון בשפתיים או בגפיים, חום; תסמינים אלה עלולים להעיד על פגיעה ריאתית חריפה שהטיפול בה כרוך בעירוי<br>• (TRALI - transfusion related acute lung injury).<br>חום גוף מעל 37.8°C עלול להעיד על זיהום.<br>חשוב לדווח לרופא שלך על כל תופעת לוואי המדאיגה אותך. תוכל/י לבקש מהרופא שלך את המידע המלא שזמין למומחי הבריאות.<br>בכל מקרה שבו הינך מרגיש/ה תופעות לוואי שלא צוינו בעלון זה, או אם חל שינוי בהרגשתך הכללית עליך להתייעץ עם הרופא מיד. |

**מצ"ב העלון, שבו מסומנות ההחמרות המבוקשות על רקע צהוב**.
שינויים שאינם בגדר החמרות סומנו (בעלון) בצבע שונה. יש לסמן רק תוכן מהותי ולא שינויים במיקום הטקסט.

# הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 3102.50)

**תאריך** 2.04.2014

**שם תכשיר באנגלית ומספר הרישום**

Gamunex C Reg. No. 132-95-31058-00

**שם בעל הרישום** פריגו ישראל סוכנויות בע"מ, רח' לח"י 29 בני ברק 51200

טופס זה מיועד לפרוט ההחמרות בלבד !

| ההחמרות המבוקשות | | |
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| רק בעלון | טקסט נוכחי | טקסט חדש |
| arning box | **WARNING:**<br>**RENAL DYSFUNCTION AND ACUTE RENAL FAILURE**<br>• **Rena l dysfunction, acute renal failure, osmotic nephrosis, and death may occur with immune globulin intravenous (IGIV) products in predisposed patients. Patients predisposed to renal dysfunction include those with any degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic** | **WARNING:**<br>**THROMBOSIS, RENAL DYSFUNCTION AND ACUTE RENAL FAILURE**<br>• **Throbmosi s may occur with immune globulin products, including GAMUNEX-C. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors. (see *Warnings and Precautions* [5.4], *Patient Counseling Information* [17])**<br>• **For** |

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| | **patients at risk of thrombosis, administer GAMUNEX-C at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity. (*see Dosage and Administration* [2.5], *Warnings and Precautions* [5.4])**<br>• **Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with immune globulin intravenous (IGIV) products in predisposed patients. Patients predisposed to renal dysfunction include those with any degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs.**<br>• **Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. [1] GAMUNEX-C does not contain sucrose.**<br>• **For patients at risk of renal dysfunction or failure, administer GAMUNEX-C at the minimum concentration available and the minimum infusion rate practicable. (*see Warnings and Precautions [5.2]*)** | **drugs.**<br>• **Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. [1] GAMUNEX-C does not contain sucrose.**<br>• **For patients at risk of renal dysfunction or failure, administer GAMUNEX-C at the minimum concentration available and the minimum infusion rate practicable. (see Warnings and Precautions [5.2])** | |

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| • Visually inspect GAMUNEX-C ~~should be inspected visually~~ for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if turbid.<br>• Do not freeze. Do not use ~~Solutions~~ solutions that have been frozen ~~should not be used.~~<br>• The GAMUNEX-C vial is for single use only. GAMUNEX-C contains no preservative. Use any ~~Any~~ vial that has been entered ~~should be used~~ promptly. Discard ~~Partially~~partially used vials. ~~should be discarded.~~<br>• Infuse GAMUNEX-C ~~should be infused~~ using a separate line by itself, without mixing with other intravenous fluids or medications the subject might be receiving. The GAMUNEX-C infusion line can be flushed with 5% dextrose in water (D5/W) or 0.9% sodium chloride for injection.<br>• GAMUNEX-C is not compatible with saline. If dilution is required, GAMUNEX-C may be diluted with 5% dextrose in water (D5/W). Do not dilute with saline.No other drug interactions or compatibilities have been evaluated.<br>• Content of vials may be pooled under aseptic conditions into sterile infusion bags and infused within 8 hours after pooling.<br>• Avoid simultaneous administration of GAMUNEX-C and Heparin through a | • GAMUNEX-C should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if turbid.<br>• Do not freeze. Solutions that have been frozen should not be used.<br>• The GAMUNEX-C vial is for single use only. GAMUNEX-C contains no preservative. Any vial that has been entered should be used promptly. Partially used vials should be discarded.<br>• GAMUNEX-C should be infused using a separate line by itself, without mixing with other intravenous fluids or medications the subject might be receiving.<br>• GAMUNEX-C is not compatible with saline. If dilution is required, GAMUNEX-C may be diluted with 5% dextrose in water (D5/W). No other drug interactions or compatibilities have been evaluated.<br>• Content of vials may be pooled under aseptic conditions into sterile infusion bags and infused within 8 hours after pooling.<br>• Do not mix with immune globulin | **.1**<br><br>**reparation and Handling** |

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| single lumen delivery device due to GAMUNEX-C, Heparin incompatibilities. Flush Heparin Lock (Hep-Lock) through which GAMUNEX-C was administered with 5% dextrose in water (D5/W) or 0.9% sodium chloride for injection, and do not flush with Heparin. See table below.<br><br>dditional Solutions / ilutio n / ine Flush / elivery Device Flush<br>% Dextrose in water / es / es / es<br>.9% Sodium Chloride / o / es / es<br>eparin / o / o / o<br><br>• Do not mix with immune globulin intravenous (IGIV) products from other manufacturers.<br>• Do not use after expiration date. | intravenous (IGIV) products from other manufacturers.<br>• Do not use after expiration date. | |
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| **Administer intravenously for treatment of PI, ITP and CIDP.**<br><br>GAMUNEX-C may also be administered subcutaneously for the treatment of PI.<br><br>GAMUNEX-C should be at room temperature during administration. | **Administer intravenously for treatment of PI, ITP and CIDP.**<br><br>GAMUNEX-C may also be administered subcutaneously for the treatment of PI.<br><br>GAMUNEX-C should be at room temperature during | **.5 Administration** |

GAMUNEX-C should be inspected visually for particulate matter and discoloration prior to administration, whenever the solution and container permit. Do not use if turbid and/or if discoloration is observed.

**Intravenous**

Use ~~Only~~only 18 gauge needles ~~should be used~~ to penetrate the stopper for dispensing product from the 10 mL vial; use 16 gauge needles or dispensing pins ~~should~~only ~~be used~~ with 25 mL vial sizes and larger. Insert ~~Needles~~needles or dispensing pins ~~should~~only ~~be inserted~~ once and be within the stopper area delineated by the raised ring. Penetrate ~~The~~the stopper ~~should be penetrated~~ perpendicular to the plane of the stopper within the ring.

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| AMUNEX®-C vial size | auge of needle to penetrate stopper |
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| 0 mL | 8 gauge |
| 5, 50, 100, 200 mL | 6 gauge |

Use promptly any ~~Any~~vial that has been opened~~should be used promptly~~. Discard ~~Partially~~partially used vials ~~should be discarded.~~

If dilution is required, GAMUNEX-C may be diluted with 5% dextrose in water (D5/W). Do not dilute with saline.

Infuse GAMUNEX-C using a separate line by itself, without mixing with other intravenous fluids or medications the subject might be receiving. The GAMUNEX-C

administration.

GAMUNEX-C should be inspected visually for particulate matter and discoloration prior to administration, whenever the solution and container permit. Do not use if turbid and/or if discoloration is observed.

**Intravenous**

Only 18 gauge needles should be used to penetrate the stopper for dispensing product from the 10 mL vial; 16 gauge needles or dispensing pins should only be used with 25 mL vial sizes and larger. Needles or dispensing pins should only be inserted once and be within the stopper area delineated by the raised ring. The stopper should be penetrated perpendicular to the plane of the stopper within the ring.

| AMUNEX®-C vial size | auge of needle to penetrate stopper |
|---|---|
| 0 mL | 8 gauge |
| 5, 50, 100, 200 mL | 6 gauge |

Any vial that has been opened should be used promptly. Partially used vials should be discarded.

If dilution is required, GAMUNEX-C may be diluted with 5% dextrose in water (D5/W). Do not dilute with saline.

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| infusion line can be flushed with 5% dextrose in water (D5/W) or 0.9% sodium chloride for injection. | | |
| Acute renal dysfunction/failure, acute tubular necrosis, proximal tubular nephropathy, osmotic nephrosis and death may occur upon use of IGIV products, especially those containing sucrose.(17) GAMUNEX-C does not contain sucrose.<br>Assure that patients are not volume depleted prior to the initiation of the infusion of GAMUNEX-C. Periodic monitoring of renal function and urine output is particularly important in patients judged to have a potential increased risk for developing acute renal failure. Assess renal function, including measurement of blood urea nitrogen (BUN)/serum creatinine, prior to the initial infusion of GAMUNEX-C and again at appropriate intervals thereafter. If renal function deteriorates, consider discontinuation of GAMUNEX-C. *(See Patient Counseling Information [17])* For patients judged to be at risk for developing renal dysfunction, including patients with any degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs, administer GAMUNEX-C at the minimum infusion rate practicable [less than 8 mg IG/kg/min (0.08 mL/kg/min)]. *(See Dosage and Administration [2.5])* | Assure that patients are not volume depleted prior to the initiation of the infusion of GAMUNEX-C. Periodic monitoring of renal function and urine output is particularly important in patients judged to have a potential increased risk for developing acute renal failure. Assess renal function, including measurement of blood urea nitrogen (BUN)/serum creatinine, prior to the initial infusion of GAMUNEX-C and again at appropriate intervals thereafter. If renal function deteriorates, consider discontinuation of GAMUNEX-C. *(See Patient Counseling Information [17])* For patients judged to be at risk for developing renal dysfunction, including patients with any degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs, administer GAMUNEX-C at the minimum infusion rate practicable [less than 8 mg IG/kg/min (0.08 mL/kg/min)]. *(See Dosage and Administration [2.5])* | **enal Failure** |
| **1.1 5.4.** ~~Thrombotic Events~~**Thrombosis**<br>~~Thrombotic events have~~ | **5.5 hrombotic Events**<br>Thrombotic events | **.4 Thrombosis** |

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| been reported following IGIV treatment and may occur in patients receiving IGIV treatment Thrombosis may occur following treatment with immune globulin products, including GAMUNEX-C. [9-11] Patients at riskRisk factors may include: those with a history of atherosclerosis, multiple cardiovascular risk factors, advanced age, impaired cardiac output, coagulation disorders, prolonged periods of immobilization and/or known or suspected hyperviscosity, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors. Consider baseline assessment of blood viscosity in patients at risk for hyperviscosity, including those with cryoglobulins, fasting chylomicronemia/markedly high triacylglycerols (triglycerides), or monoclonal gammopathies. For patients judged to be at risk of developing thrombotic eventthrombosis, administer GAMUNEX-C at the minimum dose and infusion rate of infusion practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity. (*see Boxed Warning, See Dosage and Administration [2.5], Patient Counseling Information* [17] *)* | have been reported following IGIV treatment and may occur in patients receiving IGIV treatment, including GAMUNEX-C. [9-11] Patients at risk may include those with a history of atherosclerosis, multiple cardiovascular risk factors, advanced age, impaired cardiac output, coagulation disorders, prolonged periods of immobilization and/or known or suspected hyperviscosity. Consider baseline assessment of blood viscosity in patients at risk for hyperviscosity, including those with cryoglobulins, fasting chylomicronemia/markedly high triacylglycerols (triglycerides), or monoclonal gammopathies. For patients judged to be at risk of developing thrombotic events, administer GAMUNEX-C at the minimum rate of infusion practicable. (*See Dosage and Administration [2.5])* | |
| **5.6 Hemolysis**<br>IGIV products, including GAMUNEX-C, may contain blood group antibodies which may act as hemolysins and induce in vivo coating of red blood cells (RBCs) with immunoglobulin, causing a positive direct | **5.7 Hemolysis**<br>IGIV products, including GAMUNEX-C, may contain blood group antibodies which may act as hemolysins and induce in vivo coating of red blood cells (RBCs) with | **.6 Hemolysis** |

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| antiglobulin reaction and, rarely, hemolysis.[12-14] Delayed hemolytic anemia can develop subsequent to IGIV therapy due to enhanced RBC sequestration, and acute hemolysis consistent with intravascular hemolysis, has been reported. (*see Adverce reactions [6]*) The following risk factors may be related to the development of hemolysis: high doses (e.g., ≥2 grams/kg, single administration or divided over several days) and non-O blood group. (29) Underlying inflammatory state in an individual patient may increase the risk of hemolysis, but its role is uncertain.(30) Monitor patients for clinical signs and symptoms of hemolysis. [15] (*see Warnings and Precautions* [5.11]), particularly patients with risk factors noted above. Consider appropriate laboratory testing in higher risk patients, including measurement of hemoglobin or hematocrit prior to infusion and within approximately 36 to 96 hours post infusion. If clinical signs and symptoms of hemolysis or a significant drop in hemoglobin or hematocrit have been observed, perform additional confirmatory laboratory testing. If transfusion is indicated for patients who develop hemolysis with clinically compromising anemia after receiving IGIV, perform adequate cross-matching to avoid exacerbating on-going hemolysis. ~~(*See Patient Counseling Information [17])* If signs and/or symptoms of hemolysis are present after GAMUNEX-C infusion, perform appropriate confirmatory laboratory testing.~~ | immunoglobulin, causing a positive direct antiglobulin reaction and, rarely, hemolysis.[12-14] Delayed hemolytic anemia can develop subsequent to IGIV therapy due to enhanced RBC sequestration, and acute hemolysis consistent with intravascular hemolysis, has been reported. Monitor patients for clinical signs and symptoms of hemolysis. [15] (*See Patient Counseling Information [17])* If signs and/or symptoms of hemolysis are present after GAMUNEX-C infusion, perform appropriate confirmatory laboratory testing. | |
| **5.11 Monitoring : Laboratory Tests**<br>• Periodic monitoring | **5.11**<br>**Laboratory Tests**<br>After infusion of IgG, the transitory rise of the various | **.11 Laboratory Tests** |

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| of renal function and urine output is particularly important in patients judged to be at increased risk of developing acute renal failure. Assess renal function, including measurement of BUN and serum creatinine, before the initial infusion of GAMUNEX-C and at appropriate intervals thereafter.<br>• Consider baseline assessment of blood viscosity in patients at risk for hyperviscosity, including those with cryoglobulins, fasting chylomicronemia/markedly high triacylglycerols (triglycerides), or monoclonal gammopathies, because of the potentially increased risk of thrombosis.<br>• If signs and/or symptoms of hemolysis are present after an infusion of GAMUNEX-C, perform appropriate laboratory testing for confirmation.<br>• If TRALI is suspected, perform appropriate tests for the presence of anti-neutrophil antibodies and anti-HLA antibodies in both the product and patient's serum.<br>**5.12 Laboratory**<br>**Tests**<br>After infusion of IgG, the transitory rise of the various passively transferred antibodies in the patient's blood may yield positive serological testing results, with the potential for misleading interpretation.<br>~~Passive transmission of antibodies to erythrocyte antigens (e.g., A, B, and D) may cause a positive direct or indirect~~ | passively transferred antibodies in the patient's blood may yield positive serological testing results, with the potential for misleading interpretation.<br>Passive transmission of antibodies to erythrocyte antigens (e.g., A, B, and D) may cause a positive direct or indirect antiglobulin (Coombs') test. Patients with known renal dysfunction or renal failure, including patients with pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or those receiving nephrotoxic agents, should be clinically assessed and monitored (BUN, creatinine), as appropriate, during therapy with GAMUNEX-C.<br>Consider baseline assessment of blood viscosity in patients at risk for hyperviscosity, including those with cryoglobulins, fasting chylomicronemia/markedly high triacylglycerols (triglycerides), or monoclonal gammopathies. | |

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| ~~antiglobulin (Coombs') test. Patients with known renal dysfunction or renal failure, including patients with pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or those receiving nephrotoxic agents, should be clinically assessed and monitored (BUN, creatinine), as appropriate, during therapy with GAMUNEX-C.~~<br><br>~~Consider baseline assessment of blood viscosity in patients at risk for hyperviscosity, including those with cryoglobulins, fasting chylomicronemia/markedly high triacylglycerols (triglycerides), or monoclonal gammopathies.~~ | | |
| **7. DRUG INTERACTIONS**<br>GAMUNEX-C may be diluted with 5% dextrose in water (D5/W). Admixtures of GAMUNEX-C with other drugs and intravenous solutions have not been evaluated. It is recommended that GAMUNEX-C be administered separately from other drugs or medications which the patient may be receiving. The product should not be mixed with IGIVs from other manufacturers.<br><br>The infusion line may be flushed before and after administration of GAMUNEX-C with D5/W or 0.9% sodium chloride for injection.<br><br>Avoid simultaneous administration of GAMUNEX-C and Heparin through a single lumen delivery device due to GAMUNEX-C, Heparin incompatibilities. | **7. RUG INTERACTIONS**<br>GAMUNEX-C may be diluted with 5% dextrose in water (D5/W). Admixtures of GAMUNEX-C with other drugs and intravenous solutions have not been evaluated. It is recommended that GAMUNEX-C be administered separately from other drugs or medications which the patient may be receiving. The product should not be mixed with IGIVs from other manufacturers.<br><br>The infusion line may be flushed before and after administration of GAMUNEX-C with D5/W.<br><br>Various passively transferred antibodies in immunoglobulin | **.**<br><br>**rug interactions** |

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| Flush Heparin Lock (Hep-Lock) through which GAMUNEX-C was administered with 5% dextrose in water (D5/W) or 0.9% sodium chloride for injection, and do not flush with Heparin.<br><br>Various passively transferred antibodies in immunoglobulin preparations can confound the results of serological testing.<br><br>Passive transfer of antibodies may transiently interfere with the immune response to live virus vaccines such as measles, mumps, rubella and varicella. Inform the immunizing physician of recent therapy with GAMUNEX-C so that appropriate measures may be taken (*see Patient Counseling Information [17])* | preparations can confound the results of serological testing.<br><br>Passive transfer of antibodies may transiently interfere with the immune response to live virus vaccines such as measles, mumps, rubella and varicella. Inform the immunizing physician of recent therapy with GAMUNEX-C so that appropriate measures may be taken (*see Patient Counseling Information [17])* | |
| **10.OVERDOSE**<br><br>With intravenous administration, overdose of GAMUNEX-C may lead to fluid overload and hyperviscosity. Patients at risk of complications of fluid overload and hyperviscosity include elderly patients and those with cardiac renal impairment. | | **0 Overdose** |
| ~~Inform~~ Instruct patients to immediately report the following signs and symptoms to their healthcare provider:<br>• Decreased urine output, sudden weight gain, fluid | Inform patients to immediately report the following signs and symptoms to their healthcare provider:<br>• Decreased | **7. PATIENT COUNSELING INFORMATION** |

**[EO1] הערות עם:** *New section with content from Warnings and Precautions*

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| retention/edema, and/or shortness of breath. (*See Warnings and Precautions [5.2])*<br>• Symptoms of thrombosis which may include: pain and/or swelling of an arm or leg with warmth over the affected area, discoloration of an arm or leg, unexplained shortness of breath, chest pain or discomfort that worsens on deep breathing, unexplained rapid pulse, numbness or weakness on one side of the body. ~~Acute chest pain, shortness of breath, leg pain, and swelling of the legs/feet~~ (*see Warnings and Precautions [~~5.5~~5.4])*<br>• Severe headache, neck stiffness, drowsiness, fever, sensitivity to light, painful eye movements, nausea, and vomiting. (*see Warnings and Precautions [5.~~6~~5])*<br>• Increased heart rate, fatigue, yellowing of the skin or eyes, and dark-colored urine (*see Warnings and Precautions. [5.~~7~~6])*<br>• Trouble breathing, chest pain, blue lips or extremities, and fever. (*see Warnings and Precautions [5.~~8~~7])*<br><br>Inform patients that GAMUNEX-C is made from human plasma and may contain infectious agents that can cause disease. While the risk GAMUNEX-C can transmit an infectious agent has been reduced by screening plasma donors for prior exposure, testing donated plasma, and by inactivating or removing certain viruses during manufacturing, patients should report any symptoms that concern them. (*see Warnings and Precautions [5.~~10~~9])*<br><br>Inform patients that | urine output, sudden weight gain, fluid retention/edema, and/or shortness of breath. (*See Warnings and Precautions [5.2])*<br>• Acute chest pain, shortness of breath, leg pain, and swelling of the legs/feet (*see Warnings and Precautions [5.5])*<br>• Severe headache, neck stiffness, drowsiness, fever, sensitivity to light, painful eye movements, nausea, and vomiting. (*see Warnings and Precautions [5.6])*<br>• Increased heart rate, fatigue, yellowing of the skin or eyes, and dark-colored urine (*see Warnings and Precautions. [5.7])*<br>• Trouble breathing, chest pain, blue lips or extremities, and fever. (*see Warnings and Precautions [5.8])*<br>Inform patients that GAMUNEX-C is made from human plasma and may contain infectious agents that can cause disease. While the risk GAMUNEX-C can transmit an infectious agent has been reduced by screening plasma donors for prior exposure, testing donated plasma, and by inactivating or removing certain viruses during manufacturing, patients should report any symptoms that concern them. (*see Warnings and Precautions [5.10])*Inform patients that GAMUNEX-C can interfere with their immune response to live viral vaccines such as measles, mumps and rubella. Inform patients to notify their healthcare | |

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| GAMUNEX-C can interfere with their immune response to live viral vaccines such as measles, mumps and rubella. Inform patients to notify their healthcare professional of this potential interaction when they are receiving vaccinations. (*see Drug Interaction [7]*)<br><br>~~Home Treatment for Primary Humoral Immunodeficiency with Subcutaneous **InfusionSelf**~~ **Administration : Subcutaneous Administration Only**<br>Provide the patient with instructions on subcutaneous infusion for home treatment, if the physician believes that home administration is appropriate for the patient. Include the type of equipment to be used along with its maintenance, proper infusion techniques, selection of appropriate infusion sites (e.g., abdomen, thighs, upper arms, and/or lateral hip), maintenance of a treatment diary, and measures to be taken in case of adverse reactions in the patient instructions. | professional of this potential interaction when they are receiving vaccinations. (*see Drug Interaction [7]*) Home Treatment for Primary Humoral Immunodeficiency with Subcutaneous Infusion<br>Provide the patient with instructions on subcutaneous infusion for home treatment, if the physician believes that home administration is appropriate for the patient. Include the type of equipment to be used along with its maintenance, proper infusion techniques, selection of appropriate infusion sites (e.g., abdomen, thighs, upper arms, and/or lateral hip), maintenance of a treatment diary, and measures to be taken in case of adverse reactions in the patient instructions<br>Rx only | |

**מצ"ב העלון, שבו מסומנות ההחמרות המבוקשות על רקע צהוב.**
שינויים שאינם בגדר החמרות סומנו (בעלון) בצבע שונה. יש לסמן רק תוכן מהותי ולא שינויים במיקום הטקסט.

**הועבר בדואר אלקטרוני בתאריך.....**