

The PROOF is in GAMUNEX-C

The *first and only* IG* therapy with both IV[†] and SC[‡] routes of administration in Primary Immunodeficiency (PI)

Important Safety Information for GAMUNEX-C

Gamunex-C, Immune Globulin Injection (Human), 10% Caprylate/Chromatography Purified, is indicated for the treatment of primary humoral immunodeficiency disease (PI), idiopathic thrombocytopenic purpura (ITP), and chronic inflammatory demyelinating polyneuropathy (CIDP).

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. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. Gamunex-C does not contain sucrose. For patients at risk of renal dysfunction or failure, administer Gamunex-C at the minimum concentration available and the minimum infusion rate practicable.

Gamunex-C is contraindicated in individuals with acute severe hypersensitivity reactions to Immune Globulin (Human). It is contraindicated in IgA deficient patients with antibodies against IgA and history of hypersensitivity.

Gamunex-C is not approved for subcutaneous use in patients with ITP or CIDP. **Due to the potential risk of hematoma formation, Gamunex-C should not be administered subcutaneously in patients with ITP.**

Hyperproteinemia, increased serum viscosity, and hyponatremia may occur in patients receiving IGIV therapy.

Thrombotic events have been reported in association with IGIV. Patients at risk for thrombotic events 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.

There have been reports of noncardiogenic pulmonary edema [Transfusion-Related Lung Injury (TRALI)], hemolytic anemia, and aseptic meningitis in patients administered with IGIV.

The high dose regimen (1g/kg x 1-2 days) is not recommended for individuals with expanded fluid volumes or where fluid volume may be a concern.

Gamunex-C is made from human plasma. Because this product is made from human plasma, it may carry a risk of transmitting infectious agents, e.g., viruses, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

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.

In clinical studies, the most common adverse reactions with Gamunex-C were headache, fever, chills, hypertension, rash, nausea, and asthenia (in CIDP); headache, cough, injection site reaction, nausea, pharyngitis, and urticaria with intravenous use (in PI) and infusion site reactions, headache, fatigue, arthralgia and pyrexia with subcutaneous use (in PI); and headache, vomiting, fever, nausea, back pain, and rash (in ITP).

The most serious adverse reactions in clinical studies were pulmonary embolism (PE) in one subject with a history of PE (in CIDP), an exacerbation of autoimmune pure red cell aplasia in one subject (in PI), and myocarditis in one subject that occurred 50 days post-study drug infusion and was not considered drug related (in ITP).

*IG=Immune globulin; †IV=Intravenous; ‡SC=Subcutaneous.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see adjacent page for brief summary of GAMUNEX-C full Prescribing Information.

Evidence based. Patient proven.

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To get GAMUNEX-C call 1-888-MY-GAMUNEX (694-2686)

USA Customer Service 1-800-243-4153

Clinical Communications 1-800-520-2807

Reimbursement Helpline 1-877-827-3462

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www.gamunex-c.com

January 2011

GX01-0111

gamunex-c
immune globulin injection (human), 10%
caprylate/chromatography purified

GAMUNEX[®]-C

Immune Globulin Injection (Human) 10% Caprylate/Chromatography Purified

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use GAMUNEX[®]-C safely and effectively. See full prescribing information for GAMUNEX-C.

**GAMUNEX-C, [Immune Globulin Injection (Human) 10%
Caprylate/Chromatography Purified]**

Initial U.S. Approval: 2003

WARNING: ACUTE RENAL DYSFUNCTION and FAILURE

*See full prescribing information
for complete boxed warning.*

- **Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with immune globulin intravenous (IGIV) products in predisposed patients.**
- **Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. GAMUNEX-C does not contain sucrose.**
- **For patients at risk of renal dysfunction or failure, administer GAMUNEX-C at the minimum concentration available and the minimum infusion rate practicable.**

-----INDICATIONS AND USAGE-----

GAMUNEX-C is an immune globulin injection (human) 10% liquid indicated for treatment of:

- Primary Humoral Immunodeficiency (PI)
- Idiopathic Thrombocytopenic Purpura (ITP)
- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

-----CONTRAINDICATIONS-----

- Anaphylactic or severe systemic reactions to human immunoglobulin
- IgA deficient patients with antibodies against IgA and a history of hypersensitivity

-----WARNINGS AND PRECAUTIONS-----

- IgA deficient patients with antibodies against IgA are at greater risk of developing severe hypersensitivity and anaphylactic reactions. Have epinephrine available immediately to treat any acute severe hypersensitivity reactions.
- Monitor renal function, including blood urea nitrogen, serum creatinine, and urine output in patients at risk of developing acute renal failure.
- GAMUNEX-C is not approved for subcutaneous use in ITP patients. Due to a potential risk of hematoma formation, do not administer GAMUNEX-C subcutaneously in patients with ITP.
- Hyperproteinemia, with resultant changes in serum viscosity and electrolyte imbalances may occur in patients receiving IGIV therapy.

- Thrombotic events have occurred in patients receiving IGIV therapy. Monitor patients with known risk factors for thrombotic events; consider baseline assessment of blood viscosity for those at risk of hyperviscosity.
- Aseptic Meningitis Syndrome (AMS) has been reported with GAMUNEX-C and other IGIV treatments, especially with high doses or rapid infusion.
- Hemolytic anemia can develop subsequent to IGIV therapy due to enhanced RBC sequestration. Monitor patients for hemolysis and hemolytic anemia.
- Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]).
- Volume overload
- GAMUNEX-C is made from human plasma and may contain infectious agents, e.g., viruses and, theoretically, the Creutzfeldt-Jakob disease agent.
- Passive transfer of antibodies may confound serologic testing.

-----ADVERSE REACTIONS-----

- **PI** – The most common adverse reactions ($\geq 5\%$) with intravenous use of GAMUNEX-C were headache, cough, injection site reaction, nausea, pharyngitis and urticaria. The most common adverse reactions ($\geq 5\%$) with subcutaneous use of GAMUNEX-C were infusion site reactions, headache, fatigue, arthralgia and pyrexia.
- **ITP** – The most common adverse reactions during clinical trials (reported in $\geq 5\%$ of subjects) were headache, vomiting, fever, nausea, back pain and rash.
- **CIDP** – The most common adverse reactions during clinical trials (reported in $\geq 5\%$ of subjects) were headache, fever, chills, hypertension, rash, nausea and asthenia.

To report SUSPECTED ADVERSE REACTIONS, contact Talecris Biotherapeutics, Inc. at 1-800-520-2807 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

-----DRUG INTERACTIONS-----

- The passive transfer of antibodies may transiently interfere with the response to live viral vaccines, such as measles, mumps and rubella. Passive transfer of antibodies may confound serologic testing.

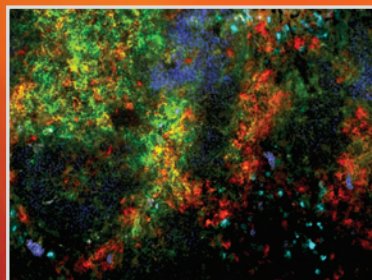
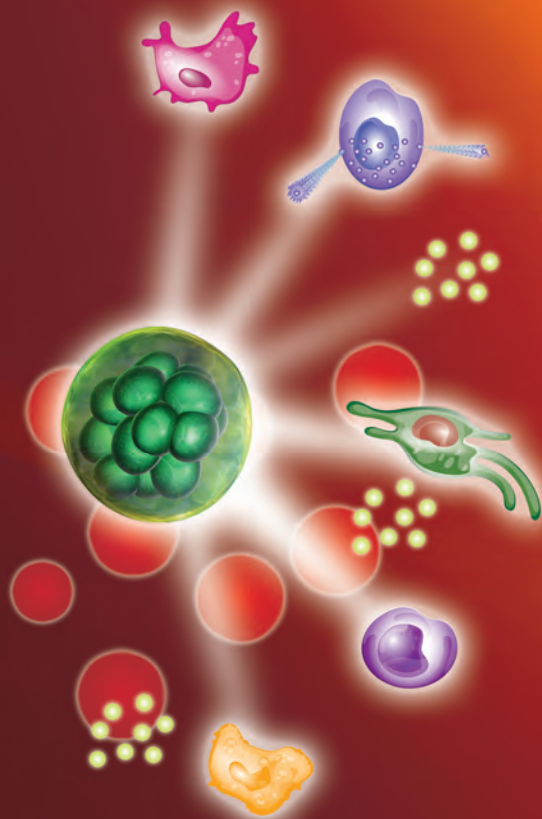
-----USE IN SPECIFIC POPULATIONS-----

- **Pregnancy:** no human or animal data. Use only if clearly needed.
- **Geriatric:** In patients over 65 years of age do not exceed the recommended dose, and infuse GAMUNEX-C at the minimum infusion rate practicable.

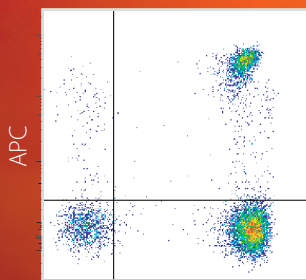
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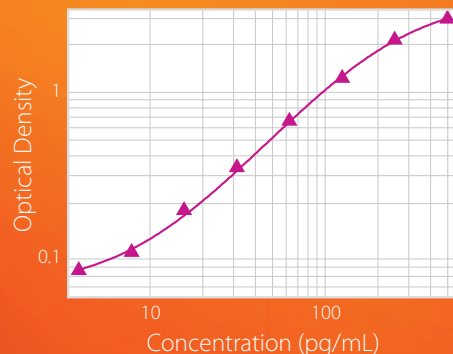
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Visit our booth at *The American Association of Immunologists 98th Annual Meeting May 13th – 17th, 2011, in San Francisco!*

Special Alert

pbl **interferon**source



PBL InterferonSource Announces World's First Interferon Multiplex Kit

VeriPlex™ Multiplex ELISA tool benefits autoimmunity and inflammation researchers

What is the VeriPlex™ Multiplex ELISA array?

The PBL *VeriPlex™* Interferon multiplex ELISA array is a quantitative ELISA-based test where 9 distinct capture antibodies have been adsorbed to each well of a 96-well plate in a defined 3x3 array. The ability to assess multiple cytokines in one assay means far less work than running individual assays.

Which cytokines can be assayed in this kit?

Human Interferons-alpha, -beta, -gamma, -omega, -lambda, Interleukin-1 alpha, Interleukin-6, TNF-alpha, and IP-10 levels can be measured.

How much sample size is required?

Using less than 30 µl of sample, up to 84 different samples can be assayed for all 9 unique analytes in less than 2.5 hours using one *VeriPlex™* ELISA leaving your precious samples for additional assays.

What is the typical sensitivity and specificity of the VeriPlex™ multiplex ELISA Arrays?

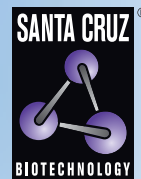
Sensitivity is system dependent. It typically ranges between 30 pg/ml to less than 5 pg/ml. All of the antibodies used in the *VeriPlex™* Human Interferon Multiplex ELISA have been subject to a rigorous and comprehensive cross reactivity protocol and verified to be non-cross reactive with any other system on the array. This means that unique cytokine profiles or “fingerprints” can be generated among different patient samples or disease states, allowing true subpopulation analysis.

How can one learn more?

**Call +1.732.777.9123 or visit us at
www.interferonsource.com/multiplex
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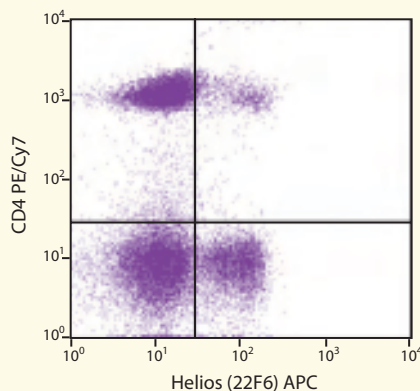
Human LAP (TGF- β)
to identify activated Tregs

Human N-Cadherin
for stem cell and adhesion studies

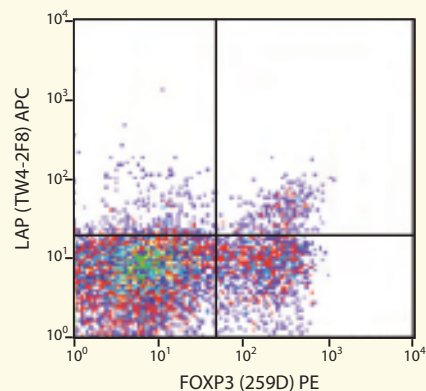
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Human PBMCs were stimulated with anti-CD3/CD28 and rhIL-2 for 24 hours; surface stained with anti-LAP APC, followed by fixation and permeabilization with BioLegend's FOXP3 Fix/Perm Buffer Set, then stained with anti-FOXP3 (clone 259D) PE (gated on CD4⁺ lymphocytes).



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Department of Pathology
University of Utah School of Medicine

The Department of Pathology at the University of Utah School of Medicine and ARUP Laboratories, Inc. is seeking a Medical Director of the Microbial Immunology Laboratory at ARUP. The successful candidate will have an M.D. and/or Ph.D. degree. Certification by the American Board of Pathology or the American Board of Medicine with additional certification in medical immunology or experience in a clinical immunology laboratory is mandatory. The successful candidate must also have a strong record of scholarly activity and either already have or be appropriate to apply for federal grants in basic or clinical research in immunology or host resistance. This individual will be expected to provide technical, clinical, administrative, teaching, research, and academic leadership. Faculty rank (Assistant, Associate, or Professor) and salary will be commensurate with experience.

Send a letter of intent and current curriculum vitae with bibliography to:

Harry R. Hill, M.D.
Associate Chair of Pathology
Department of Pathology
University of Utah
50 North Medical Dr. Room 5B114
Salt Lake City, UT 84132
U.S.A.

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As a patient-focused organization, the University of Utah Health Sciences exists to enhance the health and well-being of people through patient care, research and education. Success in this mission requires a culture of collaboration, excellence, leadership, and respect. The Health Sciences Center seeks faculty and staff who are committed to the values of compassion, collaboration, innovation, responsibility, diversity, integrity, quality and trust that are integral to our mission.

The University of Utah values candidates who have experience working in settings with students from diverse backgrounds, and possess a demonstrated commitment to improving access to higher education for historically underrepresented students.

Tumor Immunology Program Director
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CHICAGO, IL

The Rush University Cancer Center is seeking a Director for the new Tumor Immunology Program. This recruitment is part of a key strategic growth initiative for the Department of Immunology & Microbiology in partnership with the Rush University Cancer Center.

We are seeking candidates pursuing ground-breaking research in basic and/or translational tumor immunology and who bring innovative technology and expertise to the understanding the molecular and/or cellular mechanisms of tumor immunity. The Program includes established investigators in HIV and viral immunology, T cell biology, cancer and inflammation and tumor immunotherapy. The applicant should have a Ph.D., M.D., or equivalent degree; demonstrated interest in tumor immunology research; academic stature in the field, and have a track record in developing a competitive independent research program. The ideal candidate would complement the existing areas of research and actively pursue collaborations with basic scientists and clinical investigators.

Motivated candidates with a record of achievement and a commitment to excellence are encouraged to apply. Please submit a cover letter, curriculum vitae, and a brief statement of current and future research interests to Courtney Kammer. Applications are being considered through March 1, 2011. Competitive salary and benefits will be commensurate with experience. Rush is an Equal Opportunity Employer.

Please Contact:

Courtney Kammer - Director, Faculty Recruitment
Rush University Medical Center
312-942-7376 - Courtney_Kammer@rush.edu



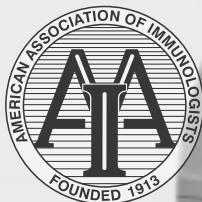
GRIP

Grant Review for Immunologists Program

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AAI is pleased to offer a program to match new PI's with established PI's who have significant, successful grant writing careers. The Grant Review for Immunologists Program (GRIP) invites new PI's to submit an outline or NIH-style abstract to the GRIP coordinator who, with the assistance of a small volunteer subcommittee, will attempt to match the topic of the proposal with the research experience of an established PI. Matches will be made as quickly as possible to allow new PI's to meet upcoming NIH grant deadlines. Participation is strictly voluntary and is not intended to supplant internal mentoring programs.

GRIP is now accepting both new PI and established PI participants. Please send your CV and a brief description of either your potential research project (new PI's) or grant reviewing experience (established PI's) to infoaai@aai.org (please write "GRIP" in the subject line).



Program details at www.aai.org/GRIP_rd.htm