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.

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

Evidence based. Patient proven.

Talecris BIOTHERAPEUTICS

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 *Help*line 1-877-827-3462

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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 (≥5%) with intravenous use of GAMUNEX-C were headache, cough, injection site reaction, nausea, pharyngitis and urticaria. The most common adverse reactions (≥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 ≥5% of subjects) were headache, vomiting, fever, nausea, back pain and rash.
- **CIDP** – The most common adverse reactions during clinical trials (reported in ≥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.

Talecris BIOTHERAPEUTICS

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08939771/08939782-BS
Revised: October 2010

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LIST OF PROTEINS

4-1BBL
4-1BB Receptor
6 Ckine
ACAD8
ACAT2
gAcrp30/Adipolean
Activin A
ACY1
ADAT1
Adiponectin
ADRP
AITRL
Akt1
Alpha-Feto Protein (AFP)
Alpha-Galactosidase A
Angiopoietin-1 (Ang-1)
Angiopoietin-2 (Ang-2)
Angiostatin K1-3
Annexin-V
apo-SAA
Apoliprotein A-1
Apoliprotein E2
Apoliprotein E3
Apoliprotein E4
APRIL
Artemin
ATF2
Aurora A
Aurora B
BAFF
BAFF Receptor
BCA-1 / BLC / CXCL13
BCMA
BD-1
BD-2
BD-3
BDNF
Bivalirudin
BMP-2
BMP-4
BMP-7
BMP-13
sBMPR-1A
Brain Natriuretic Protein
BRAK
Breast Tumor Antigen
C5a
C5L2 Peptide
C-10
C-Reactive Protein
C-Src
Calbindin D-9K
Calbindin D-28K
Calbindin D-29K
Calmodulin
Calcitonin Acetate
Carbonic Anhydrase III
Carcino-embryonic Antigen
Cardiotrophin-1
Caspase-3
Caspase-6
CD4
CD14
CD22
CD40 Ligand / TRAP
CD95 / sFas Ligand
CD105 / Endoglin
CHIPS
CNTF
Collagen
CREB
CTACK/CCL27
CTGF
CTGFL/WISP-2
CTLA-4/Fc
CXCL16
Cytokeratin 8
DEP-1
Desmopressin
Disulfide Oxidoreductase
E-selectin
ECGF
EGF
Elafin/SKALP
EMAP-II
ENA-78
Endostatin
Enteropeptidase
Eotaxin
Eotaxin-2
Eotaxin-3 (TSC)
EPHB2
EPHB4
Eptifbatide
Erk-2
Erythropoietin (EPO)
Exodus-2
Fas Ligand
Fas Receptor
FGF-1 (acidic)
FGF-2 (basic)
FGF-4
FGF-5
FGF-6
FGF-7/ KGF
FGF-8
FGF-9
FGF-10
FGF-16
FGF-17
FGF-18
FGF-19
FGF-20
sFGFR-1 (IIIc) / Fc Chimera
sFGFR-2 (IIIc) / Fc Chimera
sFGFR-3 / Fc Chimera
sFGFR-4 / Fc Chimera
sFlt-1 (native)
sFlt-1 (D3)
sFlt-1 (D4)
sFlt-1 (D5)
sFlt-1 (D7)
Flt3-Ligand
sFlt-4
sFlt-4/ Fc Chimera
Follistatin
FSH
Fractalkine/ CX3C
G-CSF
α-Galactosidase A
Galectin-1
Galectin-3
Gastrointestinal CA
GCP-2
GDF-3
GDF-9
GDF-11
GDNF
GLP-1
Glucagon
Goserelin
GM-CSF
GPBB
GROα
GROβ
GROγ
GRO/MGSA
Growth Hormone
Growth Hormone BP
GST-p21/WAF-1
HB-EGF
HCC-1
HGF
Histdyl-tRNA synthetase
Histrelin
HRG1-β1
I-309
I-TAC
IFN-α
IFN-α A
IFN-α 2a
IFN-α 2b
IFN-β
IFN-γ
IFN-Omega
IGF-I
IGF-II
proIGF-II
IGFBP-1
IGFBP-2
IGFBP-3
IGFBP-4
IGFBP-4
IGFBP-5
IGFBP-6
IGFBP-7
IL-1α
IL-1β
IL-2
IL-3
IL-4
sIL-4 Receptor
IL-5
IL-6
sIL-6 Receptor
IL-7
IL-8 (72 a.a.)
IL-8 (77 a.a.)
IL-9
IL-10
IL-11
IL-12
IL-13
IL-13 analog
IL-15
IL-16 (121 a.a.)
IL-16 (130 a.a.)
IL-17
IL-17B
IL-17D
IL-17E
IL-17F
IL-19
IL-20
IL-22
IL-31
Insulin
IP-10
JE
JNK2a1
JNK2a2
KC / CXCL1
KGF
L-asparaginase
LAG-1
LALF Peptide
LAR-PTP
LC-1
LBP
LD-78β
LDH
LEC/NCC-4
Leptin
LIGHT
LIX
LKM
LL-37
Lymphotactin
sLYVE-1
M-CSF
MCP-1 (MCAF)
MCP-2
MCP-3
MCP-4
MCP-5
MDC (67 a.a.)
MDC (69 a.a.)
MDH
MEC
Mek-1
MIA
Midkine
MIG / CXCL9
MIP-1α / CCL3
MIP-1β / CCL4
MIP-3 / CCL23
MIP-3α / CCL20
MIP-3β / CCL19
MIP-4 (PARC) / CCL18
MIP-5 / CCL15
MMP-3
MMP-7
MMP-13
Myostatin
Nanog
NAP-2
Neurturin
NFAT-1
beta-NGF
NOGGIN
NOV
NP-1
NT-1/BCSF-3
NT-3
NT-4
Ocreotide
Oncostatin M
Osteoprotegerin (OPG)
OTOR
Oxytocin
p38-α
Parathyroid Hormone
PDGF-AA
PDGF-AB
PDGF-BB
Persephin
PF-4
PIGF-1
PIGF-2
PKA α-subunit
PKC-α
PKC-γ
Pleiotrophin
PLGF-1
Polymyxin B (PMB)
PRAS40
PRL-1
PRL-2
PRL-3
Prokineticin-2
Prolactin
Protirelin
PTHrP
PTP1B
PTP-IA2
PTP-MEG2
PTP-PEST
sRANK
sRANKL
RANTES
RELM-α
RELM-β
Resistin
RPTPβ
RPTPγ
RPTPμ
SCF
SCGF-α
SCGF-β
SDF-1α
SDF-1β
Secretin
SF20
SHP-2
STAT1
c-Src
TACI
TARC
TC-PTP
TECK
TFF2
TGF-α
TGF-β1
TGF-β2
TGF-β3
Thymosin α1
sTIE-1/Fc Chimera
sTIE-2/Fc Chimera
TL-1A
TNF-α
TNF-β
sTNFR1
sTNFR2
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sTRAIL R-1 (DR4)
sTRAIL R-2 (DR5)
TSH
TSLP
TWEAK
TWEAK Receptor
Urokinase
VEGF121
VEGF145
VEGF165
VEGF-C
VEGF-C I525
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WISP-1
WISP-2
WISP-3
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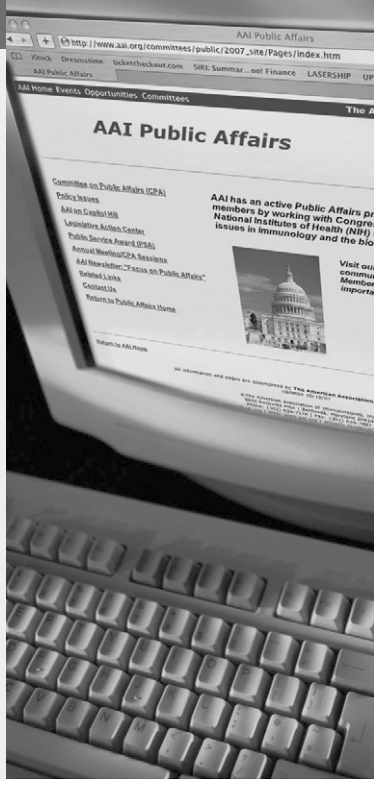

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The Department of Pathology at the University of Utah School of Medicine and ARUP Laboratories, Inc, is seeking a Medical Director of the Microbial Immunology Laboratory at ARUP. The successful candidate will have an M.D. and/or Ph.D. degree. Certification 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.

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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
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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.

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