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13th October 2025

Hospital Transfusion Committee Chairs
PLEASE CIRCULATE AS REQUIRED

Dear Colleagues

Re: Normal Immunoglobulin (Ig)-VF® to be discontinued and replaced by GamaSTAN® (Section 29 – commercial product)

As part of the change to New Zealand's plasma products portfolio Normal Immunoglobulin-VF will no longer be manufactured for New Zealand Blood Service (NZBS) by CSL Behring. Production of Normal Immunoglobulin-VF ceased in November 2022, and the current batch of product expires in November 2025.

An alternative product, GamaSTAN, has been sourced. This product will be issued under Section 29 arrangements. GamaSTAN is made from plasma/blood donations from other countries and marketed in several other countries.

How does GamaSTAN differ from Normal Immunoglobulin (Ig)-VF?

Appendix 1 includes a comparison of the two products based on their respective datasheets. The key difference to note is that GamaSTAN is supplied in a 10 mL vial.

The datasheets for both these products are attached to this notification, and the Transfusion Medicine Handbook has been updated to include GamaSTAN (https://www.nzblood.co.nz/healthcare-professionals/transfusion-medicine/transfusion-medicine-handbook/5-fractionated-products/5-4-2-gamastan).

When will GamaSTAN be available?

GamaSTAN is currently being sent out to NZBS hub sites. Blood Banks are encouraged to order early given the expiry of Normal Immunoglobulin-VF on the 24th of November 2025. Ideally, Blood Banks will continue to use up their current inventories of Normal Immunoglobulin-VF until this date.

Please direct any queries to plasmaproductschange@nzblood.co.nz

Thank you for your support in ensuring a safe and effective move to these transitioned products.

Yours faithfully

DR SARAH MORLEY
Chief Medical Officer

cc: NZBS Clinical Team, Blood Bank Team Leaders, Component Processing Team Leaders, Logistics Team Leaders, Starship Te Toka Tumai Auckland, Te Whatu Ora Immunisation Handbook

Appendix

- *111I196 GamaSTAN & Normal Immunoglobulin-VF Product Comparison*
- *111S023 Section 29 Data sheet – GamaSTAN*
- *160S013 Data Sheet - Normal Immunoglobulin-VF*

GamaSTAN & Normal Immunoglobulin-VF Product Comparison (from Data Sheets)

Characteristic	GamaSTAN, Human Immunoglobulin solution for intramuscular injection	Normal Immunoglobulin (Ig)-VF 160 mg/mL, solution for injection
Registration status	Section 29 required	Approved
Plasma source	Global donors (not including NZ) - renumerated donors	New Zealand (NZ) donors only, non-remunerated donors
Presentations	16.5 % protein solution in a 10 mL single-dose vial GamaSTAN has a pH of 4.1 to 4.8 in 0.16 to 0.26 M glycine	5 mL vial containing 800 mg of human normal immunoglobulin and Glycine (22.5 mg/mL), ready to use solution Normal Immunoglobulin-VF contains less than 0.5 mg/mL immunoglobulin A (IgA). The pH of the solution is 6.6.
Mode of action	The polyclonal antibody in GamaSTAN is a passive immunizing agent to neutralize viruses, such as hepatitis A and measles viruses, to prevent or ameliorate disease.	Normal Immunoglobulin-VF consists mainly of IgG with a broad spectrum of antibodies against various infectious agents. It has a distribution of immunoglobulin G subclasses closely proportional to that in native human plasma.
Indications	**Hepatitis A** GamaSTAN is indicated for prophylaxis following exposure to hepatitis A. The prophylactic value of GamaSTAN is greatest when given before or soon after exposure to hepatitis A. GamaSTAN is not indicated in persons with clinical manifestations of hepatitis A or in those exposed more than 2 weeks previously. **Measles** GamaSTAN is indicated to prevent or modify measles in a susceptible person exposed fewer than 6 days previously. A susceptible person is one who has not been vaccinated and has not had measles previously. • GamaSTAN may be especially indicated for susceptible household contacts of measles patients, particularly contacts under 1 year of age, for whom the risk of complications is highest. • GamaSTAN is also indicated for pregnant women without evidence of immunity. • Do not give GamaSTAN and measles vaccine at the same time. If a child is older than 12 months and has received GamaSTAN, give measles vaccine about five months later when the measles antibody titre will have disappeared. • If a susceptible child exposed to measles is immunocompromised, give GamaSTAN immediately.	**Primary and secondary hypogammaglobulinaemia** Normal Immunoglobulin-VF is indicated in the management of congenital and acquired forms of primary hypogammaglobulinaemia. It may also be of value in treating secondary forms of this disorder as in leukaemia, nephrosis and acute protein-losing enteropathy, particularly when there is a tendency to recurrent infection. **Hepatitis A prophylaxis** Routine passive protection when exposed less than one week prior for: • Household contacts no serological immunity • Common source exposure source (e.g. Hep A contaminated water) • Institutional contacts including staff in institutions where Hep A is endemic Routine prophylaxis is not recommended for school, factory, or hospital contacts. Active immunisation with Hep A vaccine is recommended.

Disclaimer: *the above information is based on a comparison of available information. It may not include all differences, including clinically important ones. The Product Information/DataSheet for each product should be reviewed in detail before prescribing*

GamaSTAN & Normal Immunoglobulin-VF Product Comparison (from Data Sheets)

Characteristic	GamaSTAN, Human Immunoglobulin solution for intramuscular injection	Normal Immunoglobulin (Ig)-VF 160 mg/mL, solution for injection
	Varicella GamaSTAN is indicated to modify varicella. • Passive immunization against varicella in immunosuppressed patients is best accomplished by use of Varicella Zoster Immune Globulin (Human). If unavailable, GamaSTAN, promptly given, may also modify varicella. **Rubella** GamaSTAN is indicated to modify rubella in exposed women who will not consider a therapeutic abortion. • Some studies suggest that the use of GamaSTAN in exposed, susceptible women can lessen the likelihood of infection and fetal damage; therefore, GamaSTAN may benefit those women who will not consider a therapeutic abortion. • Do not give GamaSTAN for routine prophylaxis of rubella in early pregnancy to an unexposed woman. **Not indicated for routine prophylaxis or treatment of viral hepatitis type B, rubella, poliomyelitis, mumps or varicella.**	**Measles prophylaxis** Normal Immunoglobulin-VF is indicated for protection against measles in persons exposed less than one week previously. It is recommended in children under six months of age whose mothers have not had the disease, in children between six months and three years of age who have not been actively immunised and in immunosuppressed contacts of the index case **Poliomyelitis prophylaxis** Recommended for susceptible contacts who have not been immunised against poliomyelitis **Rubella prophylaxis** Normal Immunoglobulin-VF can prevent or modify the clinical disease in susceptible rubella contacts if given within 72 hours of exposure, it does not prevent viraemia in such patients. It should, therefore, not be relied upon to prevent congenital malformations due to rubella if given to susceptible pregnant women during the first trimester
Dosage	**Hepatitis A prophylaxis** Exposure for household and institutional hepatitis A case contacts - 0.1 mL/kg administer within two weeks of prior exposure Administer before departure to persons traveling to areas with endemic hepatitis A: • 0.1 mL/kg if the length of stay will be up to 1 month • 0.2 mL/kg if the length of stay will be up to 2 months • 0.2 mL/kg if the length of stay will be 2 months or longer; repeat every 2 months **Rubella Modification** 0.55 mL/kg - Only administer to an exposed pregnant woman who will not consider a therapeutic abortion.	**Primary and secondary hypogammaglobulinaemia** 0.6 mL/kg body weight at intervals of one month. An additional dose should be given during the first month of treatment **Hepatitis A prophylaxis** Household/common exposure contacts: long term - 0.06 mL/kg body weight. Short term - 0.03 mL/kg body weight. For prophylaxis long term, the injections should be given 5-monthly but serological checks should be made to assess if active immunity has developed. Institutional contacts*: 0.06 mL/kg body weight Staff at institutions with endemic Hep A*: large dose (0.06 mL/kg body weight) should be offered at the time of employment, and

GamaSTAN & Normal Immunoglobulin-VF Product Comparison (from Data Sheets)

Characteristic	GamaSTAN, Human Immunoglobulin solution for intramuscular injection	Normal Immunoglobulin (Ig)-VF 160 mg/mL, solution for injection
	Measles prophylaxis Prevent or modify measles in a susceptible person exposed fewer than six days previously. • 0.5 mL/kg to a maximum dose of 5mL in immune competent infants • 0.5 mL/kg* administer to a susceptible pregnant women and immune competent adults to a maximum dose of 15mL within 6 days of exposure. *Datasheet specifies 0.25 mL/kg for susceptible persons; however Clinical Advisory Group recommends 0.5 mL/kg due to declining measles antibody levels in populations with widespread immunisation. **Varicella Modification** 0.6 mL/kg to 1.2 mL/kg administer promptly only if Varicella-Zoster Immune Globulin (Human) is unavailable.	this should be repeated at six-monthly intervals if the risk persists Administer within 1 week following exposure *Vaccination may be more appropriate **Measles prophylaxis** 0.6 mL/kg* to a max dose of 5 mL in immune-competent infants and to a max dose of 15 mL (recommended as three 5 mL injections) in pregnant women, immune-competent adults and immune-compromised/deficient children *Information taken from the Transfusion Medicine Handbook; the NZ Datasheet details 0.2 mL/kg body weight for prevention. **Poliomyelitis prophylaxis** 0.3ml/kg body weight for prevention
Method of administration	For intramuscular use only. Do not administer intravenously. • Administer GAMASTAN intramuscularly, preferably in the anterolateral aspects of the upper thigh and the deltoid muscle of the upper arm. Do not use the gluteal region as an injection site because of the risk of injury to the sciatic nerve. • Draw back on the plunger of the syringe before injection to be certain that the needle is not in a blood vessel. • Divide and inject doses greater than 10 mL into several muscle sites to reduce local pain and discomfort. An individual decision as to which muscle is injected must be made for each patient based on the volume of material to be administered. • If Hepatitis A Vaccine is recommended along with GamaSTAN, administer simultaneously but at separate anatomical sites.	Intramuscular (IM) Normal Immunoglobulin-VF should be brought to room temperature before use and given slowly by deep intramuscular injection using an appropriately sized needle. If a large dose (more than 5 mL) is required, it is advisable to administer it in divided doses at different sites. Hyaluronidase and/or a suitable local anaesthetic may be added to the injection if desired.

GamaSTAN & Normal Immunoglobulin-VF Product Comparison (from Data Sheets)

Characteristic	GamaSTAN, Human Immunoglobulin solution for intramuscular injection	Normal Immunoglobulin (Ig)-VF 160 mg/mL, solution for injection
Contraindications	• Anaphylactic or severe systemic hypersensitivity reactions to Immune Globulin (Human) • IgA deficient patients with antibodies against IgA and a history of hypersensitivity	Normal Immunoglobulin-VF is contraindicated in individuals: • with isolated immunoglobulin A (IgA) deficiency, unless they have been tested and shown not to have circulating anti-IgA antibodies. • who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections.
Warnings and precautions for usage	• Patients with known hypersensitivity to immune globulin preparations are at greater risk of developing severe hypersensitivity and anaphylactic reactions. Have epinephrine available immediately to treat any acute severe hypersensitivity reactions. • Do not administer intravenously because of the potential for serious reactions (e.g., Renal Dysfunction/Failure/Haemolysis, Transfusion-Related Acute Lung Injury [TRALI]). • GAMASTAN is made from human blood; it may carry a risk of transmitting infectious agents, e. g, viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. • Thrombosis may occur following treatment with immune globulin products, including GamaSTAN. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of oestrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.	• Normal Immunoglobulin-VF MUST NOT be administered intravenously because of the potential for anaphylactic reactions • Normal Immunoglobulin-VF should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immunoglobulin preparations • Arterial and venous thromboembolic events including myocardial infarction, stroke, deep venous thrombosis and pulmonary embolism have been associated with the use of immunoglobulins. These events may be associated with Normal Immunoglobulin-VF when it is used for primary or secondary hypogammaglobulinaemia. • This product is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses and theoretically Creutzfeldt-Jakob Disease (CJD) agents, that can cause disease.
Interaction with other medicines and other forms of interaction	Antibodies in GamaSTAN may interfere with the response to live virus vaccines such as measles, mumps, polio, rubella, and varicella. Defer live vaccine administration for up to 6 months after GamaSTAN administration.	Normal Immunoglobulin-VF should not be mixed with other pharmaceutical products except as indicated. **Vaccinations with live attenuated virus vaccines** Passively acquired antibody can interfere with response to live, attenuated virus vaccines. Administration of such vaccines should be deferred for approx. 3 months after passive immunisations. Immunoglobulins should not be administered for at least two weeks post vaccine.

GamaSTAN & Normal Immunoglobulin-VF Product Comparison (from Data Sheets)

Characteristic	GamaSTAN, Human Immunoglobulin solution for intramuscular injection	Normal Immunoglobulin (Ig)-VF 160 mg/mL, solution for injection
		Vaccinations with inactivated viruses Inactive vaccines may be administered concurrently with passive antibody (in separate syringes) to induce active immunity as is sometimes done for tetanus-prone wounds. **Interference with laboratory testing** After injection of immunoglobulin, the transitory rise of the various passively transferred antibodies in the patient's blood may result in misleading positive results in serological testing.
Undesirable effects	The most common adverse reaction reported for GamaSTAN during post-approval use was fatigue. Cases of allergic/hypersensitivity reactions including anaphylaxis have been reported. Anaphylactic reactions, although rare, have been reported following the injection of human immune globulin preparations. Anaphylaxis was more likely to occur if GAMASTAN S/D was given intravenously; therefore, GamaSTAN must be administered only intramuscularly. The following have been identified as the most frequently reported post-marketing adverse reactions: Immune system disorders, Anaphylactic reaction, hypersensitivity, Nervous system disorders, Headache, Gastrointestinal disorders, Nausea, General disorders and administration site conditions, Injection site pain, Injection site inflammation, fatigue, pyrexia	Local tenderness, erythema and stiffness may occur at the site of injection and persist for several hours. Mild pyrexia, malaise, drowsiness, urticaria True allergic responses are rare Skin lesions, headache, dizziness, nausea, generalised hypersensitivity reactions, convulsions have been reported on rare occasions
Shelf life	Not stated in package insert. Contains no preservative.	3 years The product must be used immediately after opening the vial as it does not contain antimicrobial preservative.
Special precautions for storage	Store at 2°C to 8°C Do not freeze	Store at 2°C to 8°C Refrigerate, Do not freeze, Protect from light

References:

- Section 29 Data sheet – Gamastan (111S023)
- Data Sheet - Normal Immunoglobulin-VF (160S013)
- Transfusion Medicine Handbook - Section 5 - Fractionated Products (111G021)

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use GAMASTAN safely and effectively. See full prescribing information for GAMASTAN.

GAMASTAN [immune globulin (human)], solution for intramuscular injection

Initial U.S. Approval: 1944

WARNING: THROMBOSIS

See full prescribing information for complete boxed warning

- **Thrombosis may occur with immune globulin products, including GAMASTAN. 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 (5.2), Patient Counseling Information (17)]***
- **For patients at risk of thrombosis, do not exceed the recommended dose of GAMASTAN. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity. *[Warnings and Precautions (5.2)]***

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

GAMASTAN® is a human immune globulin indicated:

- For prophylaxis following exposure to hepatitis A. (1.1)
- To prevent or modify measles in a susceptible person exposed fewer than 6 days previously. (1.2)
- To modify varicella. (1.3)
- To modify rubella in exposed women who will not consider a therapeutic abortion. (1.4)
- Not indicated for routine prophylaxis or treatment of viral hepatitis type B, rubella, poliomyelitis, mumps or varicella. (1.5)

---------- DOSAGE AND ADMINISTRATION ----------

For intramuscular use only. Do not administer intravenously.

Indication	Dosage	Instruction
Hepatitis A (2.1)	0.1 mL/kg	Administer within two weeks of prior exposure to hepatitis A.
		Administer before departure to persons traveling to areas with endemic hepatitis A:
	0.1 mL/kg	if the length of stay will be up to 1 month
	0.2 mL/kg	if the length of stay will be up to 2 months; repeat every 2 months for longer stays.
Measles (2.1)	0.25 mL/kg	Administer within 6 days of exposure.
	0.5 mL/kg	Immediately administer (maximum dose, 15 mL) to an immunocompromised child.
Varicella (2.1)	0.6 mL/kg to 1.2 mL/kg	Administer promptly if Varicella-Zoster Immune Globulin (Human) is unavailable.
Rubella (2.1)	0.55 mL/kg	Only administer to exposed pregnant women who will not consider a therapeutic abortion.

---------- DOSAGE FORMS AND STRENGTHS ----------

GAMASTAN is a sterile, 16.5% protein solution supplied in 2 mL and 10 mL single-dose vials. (3)

---------- CONTRAINDICATIONS ----------

- Anaphylactic or severe systemic hypersensitivity reactions to Immune Globulin (Human) (4)
- IgA deficient patients with antibodies against IgA and a history of hypersensitivity (4)

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

- Patients with known hypersensitivity to immune globulin preparations are at greater risk of developing severe hypersensitivity and anaphylactic reactions. Have epinephrine available immediately to treat any acute severe hypersensitivity reactions. (5.1)
- Do not administer intravenously because of the potential for serious reactions (e.g., Renal Dysfunction/Failure/Hemolysis, Transfusion-Related Acute Lung Injury [TRALI]). (5.3)
- GAMASTAN is made from human blood; it may carry a risk of transmitting infectious agents, e. g, viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. (5.4)

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

The most common adverse reaction reported for GAMASTAN® S/D [immune globulin (human)] during post-approval use was fatigue.

To report SUSPECTED ADVERSE REACTIONS, contact Grifols Therapeutics LLC at 1-800-520-2807 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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

- Defer live vaccine administration for up to 6 months. (7)

See 17 for PATIENT COUNSELING INFORMATION. **Revised: 8/2022**

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the Full Prescribing Information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: THROMBOSIS

- **Thrombosis may occur with immune globulin products, including GAMASTAN. 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 (5.2), Patient Counseling Information (17)]***
- **For patients at risk of thrombosis, do not exceed the recommended dose of GAMASTAN. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity. *[Warnings and Precautions (5.2)]***

1 INDICATIONS AND USAGE

GAMASTAN is a human immune globulin indicated for:

1.1 Hepatitis A

GAMASTAN is indicated for prophylaxis following exposure to hepatitis A.[1,2] The prophylactic value of GAMASTAN is greatest when given before or soon after exposure to hepatitis A. GAMASTAN is not indicated in persons with clinical manifestations of hepatitis A or in those exposed more than 2 weeks previously.

1.2 Measles (Rubeola)

GAMASTAN is indicated to prevent or modify measles in a susceptible person exposed fewer than 6 days previously.[3] A susceptible person is one who has not been vaccinated and has not had measles previously.

- GAMASTAN may be especially indicated for susceptible household contacts of measles patients, particularly contacts under 1 year of age, for whom the risk of complications is highest.[3]
- GAMASTAN is also indicated for pregnant women without evidence of immunity.
- Do not give GAMASTAN and measles vaccine at the same time. If a child is older than 12 months and has received GAMASTAN, give measles vaccine about five months later when the measles antibody titer will have disappeared.[3,4] *[see Drug Interactions (7)]*

  If a susceptible child exposed to measles is immunocompromised, give GAMASTAN immediately.

1.3 Varicella

GAMASTAN is indicated to modify varicella.

- Passive immunization against varicella in immunosuppressed patients is best accomplished by use of Varicella Zoster Immune Globulin (Human). If unavailable, GAMASTAN, promptly given, may also modify varicella.[5,6]

1.4 Rubella

GAMASTAN is indicated to modify rubella in exposed women who will not consider a therapeutic abortion.

- Some studies suggest that the use of GAMASTAN in exposed, susceptible women can lessen the likelihood of infection and fetal damage; therefore, GAMASTAN may benefit those women who will not consider a therapeutic abortion.[7]
- Do not give GAMASTAN for routine prophylaxis of rubella in early pregnancy to an unexposed woman.[7]

1.5 Limitations of Use

- GAMASTAN is not standardized with respect to antibody titers against hepatitis B surface antigen (HBsAg) and must not be used for prophylaxis of viral hepatitis type B. Prophylactic treatment to prevent hepatitis B can best be accomplished with use of Hepatitis B Immune Globulin (Human), often in combination with Hepatitis B Vaccine.[8]
- GAMASTAN is not indicated for routine prophylaxis or treatment of rubella, poliomyelitis, mumps, or varicella.

2 DOSAGE AND ADMINISTRATION

For intramuscular use only.

Do not administer intravenously.

2.1 Dose

Indication	Dosage	Instruction
Prophylaxis for exposure to hepatitis A	0.1 mL/kg*	Administer within two weeks of prior exposure for household and institutional hepatitis A case contacts.
		Administer before departure to persons traveling to areas with endemic hepatitis A:
	0.1 mL/kg	if the length of stay will be up to 1 month[9,10]
	0.2 mL/kg	if the length of stay will be up to 2 months[9,10]
	0.2 mL/kg	if the length of stay will be 2 months or longer; repeat every 2 months.[9,10]
Prevent or modify measles in a susceptible person exposed fewer than six days previously	0.25 mL/kg†	Administer to a susceptible person within 6 days of exposure.
	0.5 mL/kg	Immediately administer (maximum dose, 15 mL) to an immuno-compromised child.
Modify varicella	0.6 mL/kg to 1.2 mL/kg	Administer promptly only if Varicella-Zoster Immune Globulin (Human) is unavailable.
Modify rubella only in an exposed woman who will not consider a therapeutic abortion	0.55 mL/kg	Only administer to an exposed pregnant woman who will not consider a therapeutic abortion.

* 0.05 milliliter per pound
† 0.11 milliliter per pound

2.2 Preparation and Handling

- If the product shows any sign of tampering, do not use it and notify Grifols Therapeutics LLC immediately [1-800-520-2807].
- Visually inspect parenteral drug products for particulate matter and discoloration prior to administration, whenever solution and container permit. GAMASTAN is a clear or slightly opalescent, and colorless to pale yellow sterile solution.

2.3 Administration

- Administer GAMASTAN intramuscularly, preferably in the anterolateral aspects of the upper thigh and the deltoid muscle of the upper arm. Do not use the gluteal region as an injection site because of the risk of injury to the sciatic nerve.[4] *[see Warnings and Precautions (5.3)]*
- Draw back on the plunger of the syringe before injection in order to be certain that the needle is not in a blood vessel. *[see Warnings and Precautions (5.3)]*
- Divide and inject doses greater than 10 mL into several muscle sites to reduce local pain and discomfort. An individual decision as to which muscle is injected must be made for each patient based on the volume of material to be administered.
- If Hepatitis A Vaccine is recommended along with GAMASTAN, administer simultaneously but at separate anatomical sites.

3 DOSAGE FORMS AND STRENGTHS

GAMASTAN is a sterile, 16.5% protein solution supplied in 2 mL and 10 mL single-dose vials.

4 CONTRAINDICATIONS

GAMASTAN is contraindicated in:

- Anaphylactic or severe systemic hypersensitivity reactions to immune globulin (human).[11] *[see Warnings and Precautions (5.1)]*
- IgA deficient patients with antibodies against IgA and a history of hypersensitivity.[11]

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

Administer GAMASTAN cautiously to patients with a history of prior systemic allergic reactions following the administration of human immunoglobulin preparations.[11] Have epinephrine available for treatment of acute allergic symptoms, should they occur.

Do not perform skin tests. In most patients the intradermal injection of concentrated gamma globulin solution with its buffers causes a localized area of inflammation which can be misinterpreted as a positive allergic reaction. In actuality, this does not represent an allergy; rather, it is localized tissue irritation of a chemical nature. Misinterpretation of the results of such tests can lead the physician to withhold beneficial human immunoglobulin from a patient who is not actually allergic to this material.

5.2 Thrombosis

Thrombosis may occur following treatment with immune globulin products, including GAMASTAN® [immune globulin (human)].[12-14] 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.

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 at risk of thrombosis, do not exceed the recommended dose of GAMASTAN. 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, Patient Counseling Information (17)]*

5.3 Systemic Reactions

Inject intramuscularly only. Do not administer GAMASTAN intravenously because of the potential for serious reactions (e.g., Renal Dysfunction/Failure/Hemolysis, Transfusion-Related Acute Lung Injury [TRALI]). Do not inject into a blood vessel. *[see Dosage and Administration (2.3)]*

5.4 Transmissible Infectious Agents

GAMASTAN is made from human blood and may carry a risk of transmitting infectious agents, e. g, viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. GAMASTAN is purified from human plasma obtained from healthy donors. When medicinal biological products are administered, infectious diseases due to transmission of pathogens cannot be totally excluded. However, in the case of products prepared from human plasma, the risk of transmission of pathogens is reduced by: (1) epidemiological controls on the donor population and selection of individual donors by a medical interview and screening of individual donations and plasma pools for viral infection markers; (2) testing of plasma for hepatitis C virus (HCV), human immunodeficiency virus (HIV), hepatitis B virus (HBV), HAV, and human parvovirus (B19V) genomic material; and (3) manufacturing procedures with demonstrated capacity to inactivate/remove pathogens.

No cases of transmission of viral diseases, vCJD, or CJD have ever been identified for products manufactured with the same core manufacturing process as GAMASTAN. ALL infections suspected by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare provider to Grifols Therapeutics LLC [1-800-520-2807].

6 ADVERSE REACTIONS

The most common adverse reaction reported for GAMASTAN® S/D [immune globulin (human)] during post-approval use was fatigue.

6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use with GAMASTAN made using the previous manufacturing process, GAMASTAN S/D. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Among patients treated with GAMASTAN S/D, cases of allergic/hypersensitivity reactions including anaphylaxis have been reported. Anaphylactic reactions, although rare, have been reported following the injection of human immune globulin preparations.[11] Anaphylaxis was more likely to occur if GAMASTAN S/D was given intravenously; therefore, GAMASTAN S/D and GAMASTAN must be administered only intramuscularly.

The following have been identified as the most frequently reported post-marketing adverse reactions.

Immune system disorders	Anaphylactic reaction*, hypersensitivity*
Nervous system disorders	Headache
Gastrointestinal disorders	Nausea
General disorders and administration site conditions	Injection site pain, injection site inflammation, fatigue, pyrexia

*These reactions have been manifested by rash, flushing, and dyspnea

7 DRUG INTERACTIONS

Antibodies in GAMASTAN may interfere with the response to live virus vaccines such as measles, mumps, polio, rubella, and varicella. Defer live vaccine administration for up to 6 months after GAMASTAN administration.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no data with GAMASTAN use in pregnant women to inform a drug-associated risk. Animal reproduction studies have not been conducted with GAMASTAN. It is not known whether GAMASTAN can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. In the U.S. general population, the estimated backgrounds risk of major birth defect and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

8.2 Lactation

Risk Summary

There is no information regarding the presence of GAMASTAN in human milk, the effect on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for GAMASTAN and any potential adverse effects on the breastfed infant from GAMASTAN or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness in the pediatric population have not been established.

8.5 Geriatric Use

Safety and effectiveness in geriatric population have not been established.

11 DESCRIPTION

GAMASTAN is a clear or slightly opalescent, and colorless or pale yellow sterile solution of polyvalent human immune globulin for intramuscular administration. GAMASTAN contains no preservative. GAMASTAN is prepared from pools of human plasma collected from healthy donors by a combination of cold ethanol fractionation, caprylate precipitation and filtration, caprylate incubation, anion-exchange chromatography, nanofiltration and low pH incubation. GAMASTAN consists of 15% to18% protein at pH of 4.1 to 4.8 in 0.16 to 0.26 M glycine.

When medicinal biological products are administered, infectious diseases due to transmission of pathogens cannot be totally excluded. However, in the case of products prepared from human plasma, the risk of transmission of pathogens is reduced by epidemiological surveillance of the donor population and selection of individual donors by medical interview; testing of individual donations and plasma pools; and the presence in the manufacturing processes of steps with demonstrated capacity to inactivate/remove pathogens.

In the manufacturing process of GAMASTAN, there are several steps with the capacity for viral inactivation or removal. The main steps of the manufacturing process that contribute to the virus clearance capacity are as follows:

- Caprylate precipitation/depth filtration
- Caprylate incubation
- Depth filtration
- Column chromatography
- Nanofiltration
- Low pH final container incubation

To provide additional assurance of the pathogen safety of the final product, the capacity of the GAMASTAN manufacturing process to remove and/or inactivate viruses has been demonstrated by laboratory spiking studies on a scaled down process model using a wide range of viruses with diverse physicochemical properties.

The combination of all of the above mentioned measures provides the final product with a high margin of safety from the potential risk of transmission of infectious viruses.

The caprylate/chromatography manufacturing process was also investigated for its capacity to decrease the infectivity of an experimental agent of transmissible spongiform encephalopathy (TSE), considered as a model for the variant Creutzfeldt-Jakob disease (vCJD), and Creutzfeldt-Jakob disease (CJD) agents.[15] These studies provide reasonable assurance that low levels of vCJD/CJD agent infectivity, if present in the starting material, would be removed by the caprylate/chromatography manufacturing process.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The polyclonal antibody in GAMASTAN is a passive immunizing agent to neutralize viruses, such as hepatitis A and measles viruses, to prevent or ameliorate disease.

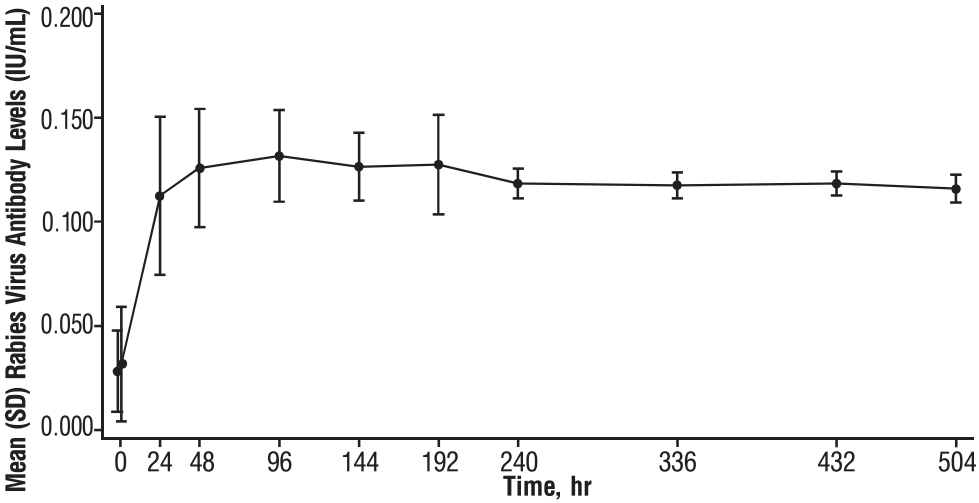
12.2 Pharmacodynamics

The prophylactic value of GAMASTAN is greatest when given before or soon after exposure.

12.3 Pharmacokinetics

Peak levels of immunoglobulin G are obtained approximately two days after intramuscular injection of GAMASTAN.[16] The half-life of IgG in the circulation of individuals with normal IgG levels is 23 days.[17]

In a clinical study, 12 healthy human subjects received a 20 IU/kg intramuscular dose of HYPERRAB® [rabies immune globulin (human)] made using the same manufacturing process as GAMASTAN. Detectable passive rabies neutralizing antibody was present by 24 hours and persisted through the 21 day follow-up evaluation period. The figure below shows the mean levels of rabies virus antibodies in IU/mL across the 21 day evaluation period and indicates that the titer remains stable during this period.



Mean (Standard Deviation) Rabies Virus Antibody Levels (IU/mL) versus Time following a Single 20 IU/kg Dose of HYPERRAB (300 IU/mL) by Intramuscular Injection

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16 HOW SUPPLIED/STORAGE AND HANDLING

GAMASTAN is supplied in 2 mL and 10 mL single dose vials. GAMASTAN contains no preservative and is not made with natural rubber latex.

NDC Number	Size
13533-335-04	2 mL vial
13533-335-12	10 mL vial

- Store GAMASTAN at 2°C to 8°C (36°F to 46°F).
- Do not freeze.
- Do not use after expiration date.

17 PATIENT COUNSELING INFORMATION

- Discuss the risks and benefits of this product with the patient, before prescribing or administering it to the patient.
- Instruct the patient to immediately report symptoms of thrombosis. These symptoms 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. *[see Warnings and Precautions (5.2)]*
- Inform the patient that GAMASTAN is made from human plasma and may carry a risk of transmitting infectious agents that can cause disease. While the risk that GAMASTAN can transmit an infectious agent has been reduced by screening plasma donors for prior exposure, testing donated plasma, and including manufacturing steps with the capacity to inactivate and/ or remove pathogens, instruct the patient to report any symptoms that concern them. *[see Boxed Warning, Warnings and Precautions (5.4)]*
- Inform the patient that GAMASTAN can interfere with their immune response to live virus 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 Interactions (7)]*

Manufactured by:

GRIFOLS

Grifols Therapeutics LLC

Research Triangle Park, NC 27709 USA

U.S. License Number 1871

3063873

NEW ZEALAND DATA SHEET

1 PRODUCT NAME

Normal Immunoglobulin-VF, 160 mg/mL, solution for injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Human Normal Immunoglobulin

Normal Immunoglobulin-VF is a sterile solution with no preservatives containing 160 mg/mL human plasma proteins. At least 98% of the protein is immunoglobulins (mainly IgG).

Normal Immunoglobulin-VF is presented in single vials as follows:

- 2 mL of solution containing 320 mg of human normal immunoglobulin.
- 5 mL of solution containing 800 mg of human normal immunoglobulin.

Normal Immunoglobulin-VF contains less than 0.5 mg/mL immunoglobulin A (IgA).

Normal Immunoglobulin-VF is manufactured from human plasma donated by New Zealand's voluntary and non-remunerated donors.

Excipients with known effect

Glycine (22.5 mg/mL)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

The pH of the solution is 6.6.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Primary and secondary hypogammaglobulinaemia

Normal Immunoglobulin-VF is indicated in the management of congenital and acquired forms of primary hypogammaglobulinaemia. It may also be of value in treating secondary forms of this disorder as in leukaemia, nephrosis and acute protein-losing enteropathy, particularly when there is a tendency to recurrent infection.

In susceptible contacts of hepatitis A, measles and poliomyelitis, Normal Immunoglobulin-VF may be of value in preventing or modifying the disease. In general, the earlier in the incubation period of these diseases Normal Immunoglobulin-VF is given, the greater its effectiveness.

Hepatitis A

Routine passive protection is recommended in persons exposed less than one week previously for the following categories of individuals:

- Household contacts of an index case, who have not already had hepatitis A or have no serological evidence of immunity to the virus.
- Common source exposures. When a vehicle such as food or water is identified as a common source of infection for multiple hepatitis cases, administration of Normal Immunoglobulin-VF should be considered for all those exposed to the source.
- Institutional contacts.
- Staff in institutions where hepatitis is endemic.

Routine prophylaxis is not recommended for school, office, factory or hospital contacts.

Rubella

Although Normal Immunoglobulin-VF can prevent or modify the clinical disease in susceptible rubella contacts if given within 72 hours of exposure, it does not prevent viraemia in such patients. It should, therefore, not be relied upon to prevent congenital malformations due to rubella if given to susceptible pregnant women during the first trimester.

Measles (Morbilli)

Normal Immunoglobulin-VF is indicated for protection against measles in persons exposed less than one week previously. It is recommended in children under six months of age whose mothers have not had the disease, in children between six months and three years of age who have not been actively immunised and in immunosuppressed contacts of the index case.

Poliomyelitis

Normal Immunoglobulin-VF is recommended for susceptible contacts who have not been immunised against poliomyelitis.

4.2 Dose and method of administration

Dose

The following dosages are recommended:

Hepatitis A

Household contacts, common source exposures: A dose of Normal Immunoglobulin-VF equivalent to 0.06 mL/kg body weight should be given for long term protection or 0.03 mL/kg body weight for short term protection. For prophylaxis long term, the injections should be given 5-monthly but serological checks should be made to assess if active immunity has developed.

The following doses of Normal Immunoglobulin-VF are recommended for persons who plan to travel in areas where hepatitis A is common*. Length of stay less than 3 months, 0.03 mL/kg body weight; 3 months or longer, 0.06 mL/kg body weight (repeat every 4–6 months).

*Institutional contacts**: 0.06 mL/kg body weight.

*Staff in institutions where hepatitis is endemic**: A large dose (0.06 mL/kg body weight) should be offered at the time of employment, and this should be repeated at six-monthly intervals if the risk persists.

* The use of hepatitis A vaccine may be more appropriate for these individuals, provided there is adequate time for active immunity to develop (7 to 10 days).

Measles

0.2 mL/kg body weight for prevention.

Poliomyelitis

0.3 mL/kg body weight.

Hypogammaglobulinaemia

0.6 mL/kg body weight at intervals of one month. An additional dose should be given during the first month of treatment.

Method of administration

If the product appears to be turbid by transmitted light or contains any sediment, it must not be used. **The product contains no antimicrobial preservative. It must, therefore, be used immediately after opening the vial.**

Normal Immunoglobulin-VF should be brought to room temperature before use, and given slowly by deep intramuscular injection using an appropriate sized needle. If a large dose (more than 5 mL) is required, it is advisable to administer it in divided doses at different sites. Hyaluronidase and/or a suitable local anaesthetic may be added to the injection if desired.

An intravenous preparation is available from CSL Behring when large doses of immunoglobulin need to be given, or when the patient has a significant haemostatic defect which may cause bleeding following intramuscular injection.

For further instructions, see section 6.6.

4.3 Contraindications

Normal Immunoglobulin-VF is contraindicated in individuals:

- with isolated immunoglobulin A (IgA) deficiency, unless they have been tested and shown not to have circulating anti-IgA antibodies.
- who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections.

4.4 Special warnings and precautions for use

Hypersensitivity

Normal Immunoglobulin-VF MUST NOT be administered intravenously because of the potential for anaphylactic reactions. Injections must be made intramuscularly, and care should be taken to draw back on the plunger of the syringe before injection in order to be certain that the needle is not in a blood vessel.

Normal Immunoglobulin-VF should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immunoglobulin preparations. In the case of shock, treatment should follow the guidelines of shock therapy.

Thromboembolism

Arterial and venous thromboembolic events including myocardial infarction, stroke, deep venous thrombosis and pulmonary embolism have been associated with the use of immunoglobulins. These events may be associated with Normal Immunoglobulin-VF when it is used for primary or secondary hypogammaglobulinaemia. Patients should be sufficiently hydrated before use of immunoglobulins. Caution should be exercised in patients with pre-existing risk factors for thrombotic events (such as advanced age, hypertension, diabetes mellitus and a history of vascular disease or thrombotic episodes, patients with acquired or inherited thrombophilic disorders, patients with prolonged periods of immobilisation, severely hypovolaemic patients, patients with diseases which increase blood viscosity).

Patients should be informed about first symptoms of thromboembolic events including shortness of breath, pain and swelling of a limb, focal neurological deficits and chest pain and should be advised to contact their physician immediately upon onset of symptoms.

Pathogen safety

This product is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses and theoretically Creutzfeldt-Jakob Disease (CJD) agents, that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain infectious agents and by testing for the presence of certain viral markers.

In addition, virus removal and inactivation procedures are included in the manufacturing process to reduce the possibility of viral transmission. This includes pasteurisation for viral inactivation and nanofiltration for virus removal.The current procedures applied in the manufacture of this product are effective against enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV), and the non-enveloped viruses, such as hepatitis A virus (HAV) and human parvovirus B19. Additionally, the product contains specific antibodies directed against human parvovirus B19.

Immunoglobulins for intramuscular injection, prepared by this process from plasma screened by current methods, have not been implicated in the transmission of viral infectious diseases including HIV. Studies using plasma spiked with HIV have shown that the Cohn cold-ethanol fractionation process produces a very large reduction in virus titre with undetectable levels in the immunoglobulin fraction. Epidemiological studies have not recognised any cluster of AIDS patients or HIV seroconversion in immunoglobulin recipients.

There is no evidence to date that parvovirus B19 can be transmitted by Normal Immunoglobulin-VF, which is known to contain antibodies to the virus and the nanofiltration step of the manufacturing process has been shown to remove such viruses (or viruses of similar size).

Despite these measures, such products may still potentially transmit disease. There is also the possibility that other known or unknown infectious agents may be present in such products. Vaccination for patients in receipt of medicinal products from human plasma should be considered where appropriate.

Genotoxicity and carcinogenicity

No genotoxicity or carcinogenicity studies have been conducted with Normal Immunoglobulin-VF. There have been no reports of such effects associated with the use of CSL Behring's plasma-derived products.

4.5 Interaction with other medicines and other forms of interaction

Normal Immunoglobulin-VF should not be mixed with other pharmaceutical products, except as indicated (see section 4.2).

Vaccinations with live attenuated virus vaccines

Passively acquired antibody can interfere with the response to live, attenuated virus vaccines. Therefore, administration of such vaccines, e.g. poliomyelitis or measles, should be deferred until approximately three months after passive immunisation. By the same token, immunoglobulins should not be administered for at least two weeks after a vaccine has been given.

Vaccinations with inactivated vaccines

Inactivated vaccines may be administered concurrently with passive antibody (although in separate syringes) to induce active immunity as is sometimes done for tetanus-prone wounds.

Interference with laboratory testing

After injection of immunoglobulin, the transitory rise of the various passively transferred antibodies in the patient's blood may result in misleading positive results in serological testing.

4.6 Fertility, pregnancy and lactation

Pregnancy

The safety of this medicinal product for use in human pregnancy has not been established in controlled clinical trials. Normal Immunoglobulin-VF should therefore only be given with caution to pregnant women.

Breast-feeding

The safety of this medicinal product for use during lactation has not been established in controlled clinical trials. Normal Immunoglobulin-VF should therefore only be given with caution to breast-feeding mothers. Immunoglobulins are excreted in breast milk, however, it is not known whether this applies to passively administered Normal Immunoglobulin-VF.

Fertility

No reproductive toxicity studies have been conducted with Normal Immunoglobulin-VF. There have been no reports of such effects associated with the use of CSL Behring's plasma-derived products.

4.7 Effects on ability to drive and use machines

No effects on ability to drive and use machines have been observed.

4.8 Undesirable effects

Summary of the safety profile

Local tenderness, erythema and stiffness may occur at the site of injection and may persist for several hours. This may occur after any intramuscular injection.

Mild pyrexia, malaise, drowsiness and urticaria have been reported occasionally after injections of immunoglobulins. True allergic responses are rare. Skin lesions, headache, dizziness, nausea, generalised hypersensitivity reactions and convulsions have been reported on rare occasions.

Adverse reactions from clinical trials

In the clinical trial with Hepatitis B Immunoglobulin, the following general and local reactions were recorded in the 58 healthy subjects (total number of events, up to and including 7 days post injection; pasteurised/unpasteurised product): malaise (20/22 events), drowsiness (13/17 events), induration (10/4 events), sensation of fever (4/4 events), chills (3/3 events), sweating (3/1 events) and warmth/heat when touched (0/4 events). There was an overall higher reporting of local tolerance adverse events at the injection site for the unpasteurised product, such as pain (32/52 events), bruising (10/22 events), redness (2/8 events) and irritation (2/4 events).

Paediatric population

The use of this product in the paediatric population has not been established in appropriate studies. To date, this population is not over-represented in spontaneous reports of adverse events associated with the use of CSL Behring's intramuscular therapeutic medicines.

Elderly population

The use of this product in the elderly populations has not been established in appropriate studies. To date, this population is not over-represented in spontaneous reports of adverse events associated with the use of CSL Behring's intramuscular therapeutic medicines.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions via https://nzphvc.otago.ac.nz/reporting/

4.9 Overdose

The consequences of overdosage are not known.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: immune sera and immunoglobulins: immunoglobulins, normal human, for extravascular administration

ATC code: J06BA01

Mechanism of action

Normal Immunoglobulin-VF consists mainly of IgG with a broad spectrum of antibodies against various infectious agents. It has a distribution of immunoglobulin G subclasses closely proportional to that in native human plasma. Adequate doses of this medicinal product may restore abnormally low immunoglobulin G levels to the normal range.

Clinical efficacy and safety

A clinical trial with Normal Immunoglobulin-VF has not been conducted.

A comparative clinical trial was conducted to investigate the effect of pasteurisation on the *in vivo* behaviour of intramuscular immunoglobulins using Hepatitis B Immunoglobulin (pasteurised and unpasteurised) as the representative of this group of products. Fifty-eight (58) healthy subjects (28 males and 30 females) each received an intramuscular injection of pasteurised (viral inactivated) or unpasteurised Hepatitis B Immunoglobulin. No significant clinical differences were observed.

5.2 Pharmacokinetic properties

Absorption and Distribution

The immunoglobulin after intramuscular administration is slowly absorbed into the recipient's circulation and reaches a maximum after a delay of 2 to 3 days. The immunoglobulin has a half-life of about 3 to 4 weeks. This half-life may vary from patient to patient.

Elimination

IgG and IgG-complexes are broken down in cells of the reticuloendothelial system.

5.3 Preclinical safety data

Animal reproduction studies have not been conducted with Normal Immunoglobulin-VF.

Normal Immunoglobulin-VF with normal human IgG as the active ingredient is derived from human plasma and acts like an endogenous constituent of plasma. Preclinical studies with repeated dose applications (chronic toxicity and carcinogenicity) cannot be reasonably performed in conventional animal models due to the development of antibodies following the application of heterologous human proteins.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycine (22.5 mg/mL)
Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

Storage after first opening:

The product does not contain an antimicrobial preservative. It must, therefore, be used immediately after opening the vial.

6.4 Special precautions for storage

Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light.

For storage after first opening, see section 6.3.

6.5 Nature and contents of container

Normal Immunoglobulin-VF for intramuscular injection is available in single dose glass vials containing 2 mL or 5 mL of solution. Both presentations contain 160 mg/mL human plasma proteins and 22.5 mg/mL glycine.

NOTE: The following specific immunoglobulins are also available:

Tetanus Immunoglobulin-VF (for intramuscular use) for passive prophylactic immunisation against tetanus.

Zoster Immunoglobulin-VF (for intramuscular use) for prevention of varicella/zoster infection in high-risk patients, e.g. patients with malignant disease or on immunosuppressive therapy.

Hepatitis B Immunoglobulin-VF (for intramuscular use) to prevent infection of persons accidentally exposed to hepatitis B virus.

NEW ZEALAND DATA SHEET

Rh(D) Immunoglobulin-VF (for intramuscular use) for prevention of haemolytic disease of the newborn.

6.6 Special precautions for disposal and other handling

Normal Immunoglobulin-VF is a sterile, ready-to-use solution.

Any unused solution must be discarded appropriately.

7 MEDICINE SCHEDULE

Prescription Medicine

8 SPONSOR

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9 DATE OF FIRST APPROVAL

11 February 1999

10 DATE OF REVISION OF THE TEXT

8 June 2022

NEW ZEALAND DATA SHEET

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
2	Addition of immunoglobulin A value.