Subcutaneous immunoglobulins (SCIg)

Subcutaneous Immunoglobulin is allocated in accordance with the Criteria for the Clinical use of Intravenous Immunoglobulin in Australia and is obtained under the National Blood Supply (NBS) arrangements or by direct order. Refer to NBA Subcutaneous immunoglobulin approved access conditions.

Subcutaneous Immunoglobulin have guidelines and approved access conditions for use. They are currently approved for use in "approved hospitals" for:

- primary immunodeficiency diseases with antibody deficiency;
- specific antibody deficiency;
- acquired hypogammaglobulinaemia secondary to haematological malignancies (chronic lymphocytic leukaemia, multiple myeloma, non-Hodgkin lymphoma and other relevant malignancies, and post-haemopoietic stem cell transplantation);
- Secondary hypogammaglobulinaemia (including iatrogenic immunodeficiency).

Refer to: National Blood Authority, Subcutaneous Immunoglobulin (SCIg).

General Patient information:

- National Blood Authority: General patient information - Immunoglobulin Treatment
- National Blood Authority: Subcutaneous Immunoglobulin Treatment

General Information:

- National Blood Authority – Subcutaneous Immunoglobulin (SCIg)
- Australian Red Cross Blood Service – Subcutaneous Immunoglobulin (SCIg)

National Blood Authority approval must be sought via BloodSTAR accessed via the National Blood Authority website via the Blood Portal.

Product choice

Comparison of subcutaneous immunoglobulin products available for supply under the National Blood Arrangements.

Available products:

- Evogam®
- Hizentra®

Ordering

BloodSTAR is the National Blood Authority web-based system that facilitates authorisation for access and management of immunoglobulin products for the treatment of medical condition identified in the criteria.

The Australian Red Cross Blood Service (ARCBS) will continue in their role as the authorisers of immunoglobulin products. If the request is not for a condition funded under the criteria, the ordering clinician is informed of the options for availability of SCIg outside the arrangements via email through BloodSTAR,

With the introduction of BloodSTAR, all current paper-based authorisation request forms and review letters will be replaced by electronic processes.

Prescribers and nurses managing immunoglobulin ordering all require access to BloodSTAR.

Registration to BloodSTAR is via the SCHHS intranet page under Transfusion Management/Immunoglobulin or alternatively via the NBA website.

SCHHS wards / units approved for SCIg training and use are:

- Nambour - Cancer Care Centre and 2C Infusion Service;
- Caloundra – Operating Room Suites (ORS) Recovery – Day Procedure Unit (DPU);
- Gympie – Chemotherapy Unit.

SCIg Program

For further information on the SCIg Program and use in the SCHHS refer to the Transfusion Clinical Nurse Consultant at: Janine.English@health.qld.gov.au.

SCHHS SCIg program forms and information

- Subcutaneous Immunoglobulin (SCIg) Home Therapy Prescription / Order;
- Order requirements;
- SCIg flowchart;
- SCIg training checklist;
- SCIg training competency;
- SCIg patient assessment form;
- SCIg treatment record and consumable supply list.

Evogam® 16% – Normal Human Subcutaneous Immunoglobulin (SCIg)

Product Information and Consumer Information

All immunoglobulins are ordered via BloodSTAR on the National Blood Authority website.
Haematological Indications
Immunological Indications

Evogam Contacts: Customer Service 1800 063 892 – 24hrs / 7 days
Medical Technical Enquiries 1800 642 865 – 24hrs / 7 days

Indications	Evogam is indicated in adults and children for replacement therapy in: • Primary Immunodeficiency Diseases (PID) and • Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment.
Precautions	• **Evogam® must not be administered intravenously or intramuscularly.** If Evogam® is inadvertently administered into a blood vessel, patients could develop shock. In the case of shock, current medical standards for shock treatment should be observed. • Certain adverse reactions may occur more frequently in patients who receive human normal immunoglobulin for the first time or, in rare cases, when there has been a long interval since previous infusion. • Evogam® should be used with caution in patients with a known allergy to constituents of the preparation. Evogam® contains traces of IgA which may provoke anaphylaxis in IgA deficient patients with anti-IgA antibodies. • Caution should be exercised in prescribing and administering Evogam® in obese patients and 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 and patients with diseases which increase blood viscosity). • Aseptic Meningitis Syndrome (AMS) has been reported to occur infrequently in association with human immunoglobulin administration. For further information on precautions refer to: Product Information
Contraindications	Evogam® is contraindicated in patients who have had a true anaphylactic reaction to the active substance or to the excipient glycine.
Incompatibilities	Must not be mixed with any other product.
Presentation	Evogam® contains human normal immunoglobulin G (IgG): • 5mL vial contains 0.8 grams of IgG • 20mL vial contains 3.2 grams of IgG.
Storage Conditions	• Shelf life is 2 years. • Store at 2°C to 8°C (Refrigerate. Do not freeze). • Protect from light. • Do not use after expiry date. • Once removed from refrigeration the product may be stored below 25°C and used within **two weeks**. The date of removal from refrigeration and the new expiry date must be noted on the outer carton.
Inspection	• Do not use if particulate matter and/or discolouration is observed. • Only clear or slightly opalescent fluids are to be administered.
Infusion Equipment	• Alcohol cleansing wipe, subcutaneous needle/s, luer lock syringes and if required an extension set. • Subcutaneous Infusion Pump if required (these pumps must be used in compliance with manufacturer's instruction). • Sterile dressing (if required).
Prior to commencement of infusion	**RIGHT PATIENT / RIGHT PRODUCT** • Medical order must be documented on the SCHHS Blood and blood products prescription form. If patients are being trained for home treatment the nurse must ensure the Patient Treatment Diary is also completed. • Home treatment – must be documented by patient in Patient Treatment Diary. • Medical staff discuss indications and use of the Evogam® with the patient / carer including possible reactions, and, the patient agrees to the infusion commencing.

	• Clinical staff explain the administration procedure to patient. A patient information brochure must be given. • Take baseline TPR and BP and oxygen saturation (in hospital only). • Allow the product to reach room temperature before infusing.
4 Hour Rule	• Complete each bottle within 4 hours of opening/piercing as contains no antimicrobial agent. • No blood product is to be stored on wards/units, if not being transfused return to the laboratory.
Home Treatment	• Home treatment should be initiated by a clinician experienced in the guidance of patients for home treatment. • The patient must be instructed in the use infusion techniques, the keeping of a treatment diary and measures to be taken in the case of severe adverse events. • Duration of instruction and number of times required will be dependent on patient understanding and competence.
Rate and Dose	• The dosage may need to be individualised for each patient dependent on the pharmacokinetic and clinical response. • The following dosage regimens are given as guidance: – A weekly dose in the range 0.05-0.15 g/kg body weight (approx. 0.3-0.9mL/kg body weight) is recommended (this corresponds to a total monthly dose of Evogam® in the range of 0.2-0.6 g/kg body weight). – Trough IgG levels should be measured in order to adjust the dose and dosage interval. – Initial infusion rate: 10mL/hour/site. The infusion rate may be gradually increased up to 20mL/hour/site as comfort and tolerability allows. – When large doses are given (>20mL), it is advisable to administer them in divided doses at different sites. (The maximum dose administered must not exceed 40mL/hour per site).
Administration	• **Evogam® is to be administered via the subcutaneous route only**, preferentially into the upper/outer arms, thighs, abdomen and/or lateral hip. • Administration methods for Evogam® include use of an infusion pump or rapid push techniques. The choice of administration technique and equipment is at the discretion of the treating healthcare professional in collaboration with the patient. **Instruction for use** • Remove the peel-off batch number from the Evogam® vial and insert into the patient diary. • Remove the protective cap from the vial and wipe the rubber stopper with alcohol. • For withdrawing Evogam®, use a sterile syringe and the supplied transfer device. • Inject air into the vial that is equivalent to the amount of Evogam® to be withdrawn. Then withdraw Evogam® from the vial. If multiple vials are required to achieve the desired amount of Evogam®, repeat this step. • Prime the administration tubing to ensure that no air is left in the tubing by filling the tubing/needle with Evogam®. • Subcutaneous infusion pump only - Follow the manufacturer's instructions for preparing the pump. • Clean the injection site(s) with antiseptic solution. • Multiple injection sites can be used simultaneously. Injection sites should be at least 5 cm apart. • Grasp the skin between two fingers and insert the needle into the subcutaneous tissue. • ***Evogam® must not be injected into a blood vessel.*** To test that no blood vessel has been accidentally hit undertake a double checking process: • Gently pull back on the syringe plunger and look to see if any blood is flowing back into the tubing. • Disconnect the syringe from the tubing and hang tubing lower than the injection site for 3-5 seconds. If blood return is noticed, remove and discard the needle and tubing. Repeat priming

	and needle insertion steps using a new needle, tubing and a new infusion site. • Secure the needle in place by applying a transparent dressing. • Infuse Evogam® slowly (subcutaneous infusion pump only - follow the manufacturer's instructions for the pump). • The infusion site may be changed if patient comfort becomes an issue. **Subcutaneous Injection via infusion pump** • Evogam® subcutaneous infusion using a NIKI pump refer to SCHHS procedure Subcutaneous infusion, Using a NIKI T34 Device.
Observations (in hospital use only)	Patients should be closely monitored and carefully observed for any adverse events throughout the infusion period and for at least 20 minutes after the infusion. • Baseline observations immediately prior to the commencement 1st infusion / 1st dose As deemed necessary through-out the infusion or in response to clinical symptoms
Adverse Effects	• Patient's naïve to immunoglobulin may experience a higher frequency of adverse effects including those of a minor nature. • In case of severe reactions the infusion must be stopped and an appropriate treatment initiated. • Type of reactions may include: – **Very Common** – infusion site reaction, fever, nausea, vomiting, diarrhoea – **Common** – chills, back pain, arthralgia, hypotension – **Rare** – allergic reactions, anaphylactic shock, thrombotic reactions. • Slowing or stopping the infusion usually allows the symptoms to subside. Assess vital signs, notify the Medical Officer, and provide emergency care as required. • Minor reactions: the infusion may be resumed at a slower rate or rate that does not result in recurrence of the symptoms once the patient is stable and has clinically improved. • In the case of serious adverse events stop the infusion and Refer to Section 18: Transfusion adverse events and reactions. • Report all adverse events to Bloodbank / Transfusion and CSL Medical Enquiries ASAP and no later than 24 hours from the event via: CSL Suspected adverse reaction report form or phoning 1800 642 865. • Report all adverse events in PRIME CI and record in the Patient health record.
Reference	• CSL Product Information, *Evogam*, 2014.

Hizentra® 20% – Normal Human Subcutaneous Immunoglobulin (SCIg)	
Product Information and Consumer Information	
All immunoglobulins are ordered via BloodSTAR on the National Blood Authority website. • Haematological Indications • Immunological Indications **Hizentra® Contacts: Customer Service** 1800 063 892 – 24hrs / 7 days **Medical Technical Enquiries** 1800 642 865 – 24hrs / 7 days	
Indications	Hizentra® is indicated in adults and children for replacement therapy in: • Primary Immunodeficiency Diseases (PID) and • Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment.
Precautions	• **Hizentra® must not be administered intravenously or intramuscularly.** If Hizentra® is inadvertently administered into a blood vessel, patients could develop shock. In the case of shock, current medical standards for shock treatment should be observed. • Certain adverse reactions may occur more frequently in patients who receive human normal immunoglobulin for the first time or, in rare cases, when there has been a long interval since previous infusion. • Known allergies: use with caution in patients with a known allergy to anti-IgA as it may cause severe hypersensitivity or anaphylaxis. • Thrombotic Events: caution should be exercised in prescribing and administering Hizentra® 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 and patients with diseases which increase blood viscosity). • An aseptic meningitis syndrome (AMS) has been reported to occur infrequently in association with human immunoglobulin administration. • Transmissible infective agents may be a possibility. • Use in pregnancy. For further information on precautions refer to: Product Information.
Contraindications	Hizentra® is contraindicated in patients who have had a true anaphylactic reaction to the active substance or to any of its excipients. Must not be used in hyperprolinaemia type I or II.
Incompatibilities	Must not be mixed with any other product.
Presentation	Hizentra® contains human normal immunoglobulin G (IgG): • 1 g in a 5 mL solution • 2 g in a 10 mL solution • 4 g in a 20 mL solution • 10 g in a 50 mL solution.
Storage Conditions	Shelf life is 2 years. Store below 25°C (Do not freeze). Keep the vial in the outer carton in order to protect from light. Do not use after expiry date.
Inspection	This product is normally clear and pale-yellow or light-brown. • Do not use if particulate matter and/or discolouration is observed. • Only clear or slightly opalescent fluids are to be administered.
Infusion Equipment	• Alcohol cleansing wipe, Subcutaneous needle/s, luer lock syringe/s and subcutaneous extension set (if required). • Sterile dressing (if required). • Subcutaneous Infusion Pump if required (these pumps must be used in compliance with manufacturer's instruction) i.e. Niki T34 or Springfuser.
Prior to commencement of	**RIGHT PATIENT/RIGHT PRODUCT** • Medical order documented on the Subcutaneous Immunoglobulin (SCIg) Home

infusion	therapy Prescription/Order form. • Home treatment – must be documented by patient in Patient Treatment Diary. • Medical Officer to discuss indications and use of Hizentra® with the patient including possible reactions. Verbal consent to be obtained and documented in the patient clinical record prior to first infusion. • Clinical staff explain the self-administration procedure to the patient. Manufacturer's patient information brochure may be given. • Take baseline TPR and BP (in hospital only). • Read the product information contained in the box. • Allow the product to reach room temperature before infusing.
4 Hour Rule	• Complete each bottle within 4 hours of opening/piercing as contains no antimicrobial agent. • No blood product is to be stored on wards/units, if not being transfused return to the laboratory.
Administration	• **Hizentra® is to be administered via the subcutaneous route only**, preferentially into the upper/outer arms, thighs, abdomen and/or lateral hip. • Administration methods for Hizentra® include use of an infusion pump, or rapid push techniques. The choice of administration technique and equipment is at the discretion of the treating healthcare professional. • The dosage may need to be individualised for each patient dependent on the pharmacokinetic and clinical response. • A loading dose of at least 0.2 to 0.5 g/kg (1.0 to 2.5 mL/kg) body weight may be required. • Maintenance doses are administered at repeated intervals to reach a cumulative monthly dose of the order of 0.4 to 0.8 g/kg (2.0 to 4.0 mL/kg) body weight. • Injection sites should be at least 5 cm apart. • The recommended initial infusion rate depends on individual needs of the patient and should not exceed 15 mL/hour/site. If well-tolerated, the infusion rate can then gradually be increased to 25 mL/hour/site. • If larger doses are given (>25 mL each site), it is advisable to administer them at multiple sites. • Trough levels should be measured in order to adjust the dose and dosage interval. **Subcutaneous Injection via infusion pump** • Hizentra® subcutaneous infusion using a subcutaneous infusion device such as but not limited to NIKI T34 or Springfuser. Refer to SCHHS procedure Subcutaneous infusion, using a NIKI T34 device. **Subcutaneous infusion for home treatment** • Home treatment should be initiated by a clinician experienced in the guidance of patients for home treatment. • The patient must be instructed in the use of a syringe driver and infusion techniques, the keeping of a treatment diary and measures to be taken in the case of severe adverse events. • Duration of instruction and number of times required will be dependent on patient understanding and competence. **Instruction for use** • Remove the protective cap from the vial and wipe the rubber stopper with alcohol. • For withdrawing Hizentra®, use a sterile syringe and the supplied transfer device. • Inject air into the vial that is equivalent to the amount of Hizentra® to be withdrawn. Then withdraw Hizentra® from the vial. If multiple vials are required

	to achieve the desired amount of Hizentra®, repeat this step. • Subcutaneous infusion pump only - Follow the manufacturer's instructions for preparing the pump- SCHHS procedure Subcutaneous infusion, Using a NIKI T34 Device. Prime the administration tubing to ensure that no air is left in the tubing by filling the tubing/needle with Hizentra®. • Clean the injection site(s) with antiseptic solution. • Grasp the skin between two fingers and insert the needle into the subcutaneous tissue. • ***Hizentra® must not be injected into a blood vessel.*** To test that no blood vessel has been accidentally hit, gently pull back on the syringe plunger and look to see if any blood is flowing back into the tubing. If you see any blood, remove and discard the needle and tubing. Repeat priming and needle insertion steps using a new needle, tubing and a new infusion site. • Secure the needle in place by applying sterile gauze or transparent dressing. • Infuse Hizentra® slowly (subcutaneous infusion pump only - follow the manufacturer's instructions for the pump). • The infusion site may be changed if patient comfort becomes an issue. • Multiple injection sites can be used simultaneously. Injection sites should be at least 5 cm apart. • Remove the peel-off label from the Hizentra® vial and insert into the patient diary.
Observations (in hospital use only)	Patients should be closely monitored and carefully observed for any adverse events throughout the infusion period and for at least 20 minutes after the infusion. • Baseline observations immediately prior to the commencement • Closely monitor the patient for the first 15 minutes • Document observations at 15 minutes; then • Hourly until completion; and • At the completion of the infusion.
Adverse Effects	• Patient's naïve to immunoglobulin may experience a higher frequency of adverse effects including those of a minor nature. • In case of severe reactions the infusion must be stopped and an appropriate treatment initiated. • Type of reactions may include: **Very Common** – injection/infusion site reaction **Common** – headache **Rare** – allergic reactions, anaphylactic shock, thrombotic reactions, chills, back pain, neck pain, arthralgia, hypotension, muscle weakness. For further rare reactions refer to Product Information • Slowing or stopping the infusion usually allows the symptoms to subside. Assess vital signs, notify the Medical Officer, and provide emergency care as required. • Minor reactions: the infusion may be resumed at a slower rate or rate that does not result in recurrence of the symptoms once the patient is stable and has clinically improved • In the case of serious adverse events stop the infusion and follow the SCHHS Blood product administration procedure: Transfusion Adverse Events and Reactions. • Report all adverse events to blood bank / transfusion and CSL Medical Enquiries ASAP and no later than 24 hours from the event via: CSL Suspected adverse reaction report form or phoning 1800 642 865. • Report all adverse events in to the PRIME CI Database.
Reference	• CSL Product Information, Hizentra, May 2013.