

Section S: Blood Product Overview –

VIVAGLOBIN[®] Immune Globulin Subcutaneous (SCIg)

CSL Behring

Page
1 of 3

DESCRIPTION of PRODUCT	1
AVAILABILITY of PRODUCT	1
STORAGE of PRODUCT	2
CLINICAL INDICATIONS (see package insert for contraindications).....	2
REQUESTS for PRIVIGEN.....	2
ADMINISTRATION of PRODUCT	2
ADDITIONAL COMMENTS	3
LINK to WEBSITE for PRESCRIBING INFORMATION	3

DESCRIPTION of PRODUCT

- Vivaglobin is a pasteurized, polyvalent human normal immunoglobulin for subcutaneous infusion.
- 16% protein solution
- Stabilizing agent is glycine with no preservatives
- Vivaglobin is manufactured from large pools of human plasma by cold alcohol fractionation
- Viral inactivation steps include precipitation and pasteurization at 60°C for 10 hours
- pH is 6.4 – 7.2
- Contains IgA ; amount not specified in product monograph.

AVAILABILITY of PRODUCT

- Product is not routinely stocked.
- Orders for specific patient must be called to Blood Transfusion Lab.
- Vivaglobin is only available in 10mL vials (1.6g)

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Section S: Blood Product Overview – VIVAGLOBIN® Immune Globulin Subcutaneous (SCIg) CSL Behring

Page
2 of 3

STORAGE of PRODUCT

- Store at 2-8°C. Do NOT freeze.
- Keep vials in storage box until use.
- Expiration date indicated on package.

CLINICAL INDICATIONS (see package insert for contraindications)

- Licensed ONLY for use in Primary Immune Deficiency (PID) as an alternative to IVIG.
- More frequent smaller doses of immune globulin will lead to stable steady-state serum IgG levels with lower IgG peak levels and higher IgG trough levels compared to monthly IVIG treatments.
- Initial weekly dose is based on previous monthly IVIG dose divided by 4 (weeks).
- Recommended dose for PID is 100-200mg/kg body weight (weekly).

REQUESTS for VIVAGLOBIN (SCIg)

- All new requests for Vivaglobin must be approved by an Immunologist
- Patient must be involved in discussion of risks, side effects including injection site reactions, and the benefits of SCIg treatment. Consent specific to SCIg treatment must be obtained.
- Initial treatments will be given in IV Therapy clinic, and patient will be instructed in subcutaneous injection technique, appropriate storage of product and required compliance with record keeping.
- A maximum 3 month supply will be issued to patient. Before issuing additional product, the patient must demonstrate their subcutaneous injection technique and their compliance with record keeping.

ADMINISTRATION of PRODUCT

- Vivaglobin is to be injected subcutaneously, preferentially in the abdomen, thighs, upper arms, and/or lateral hip.
- 15mL per injection site at a rate of 20mL/hour per site.
- Must not be infused intravenously.
- Must not be mixed with other products.

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Section S: Blood Product Overview – VIVAGLOBIN® Immune Globulin Subcutaneous (SCIg) CSL Behring

Page
3 of 3

ADDITIONAL COMMENTS

- Local injection site reactions consisting of mostly mild or moderate swelling, redness and itching have been observed with the use of Vivaglobin.
- These are generally resolved within 4 days.
- Additional information available at: <http://www.vivaglobin.com/>
- Comparison chart of the different IVIGs available in Canada is provided by the Canadian Blood Services (Plasma Protein Products Information, Product Comparison Tables, Immune Globulin Comparison Table).

LINK to WEBSITE for PRESCRIBING INFORMATION

Product monograph available at: <http://www.vivaglobin.com/pdf/PrescribingInformation.pdf>