

## CSL Behring

Dec 1<sup>st</sup>, 2009

### RE: Vivaglobin<sup>®</sup> (Immune Globulin Subcutaneous (Human)) can now be stored up to 5 months at room temperature.

Dear Healthcare Provider,

CSL Behring is pleased to announce that Vivaglobin<sup>®</sup> can now be stored for up to 5 months at room temperature. This change is effective immediately and applies to all the lots for 3mL and 10mL vial sizes currently in inventory. This will provide greater flexibility for patients who have limited storage capacity in the refrigerator or who wish to store their Vivaglobin<sup>®</sup> outside of the refrigerator.

Vivaglobin<sup>®</sup> may therefore be stored at room-temperature (not to exceed +25 °C) for up to 5 months within an overall storage period of 36 months at + 2-8 °C. If the product is stored outside the refrigerator, please add the date removed from refrigeration and note a new expiry date (*5 months later*) on the carton on space provided. The new expiry date should be 5 months from the date the product is removed from the refrigerator, or the previously stamped expiry date, whichever is shorter. Once the product is removed from refrigeration, it cannot be returned to the refrigerator<sup>1</sup>.

New Packaging with space provided to include the new 5 month room temperature storage expiration date will be available in the near future. In the meantime please follow the simple steps outlined below if you wish to immediately make use of this new feature:

1. **Remove Vivaglobin<sup>®</sup> from refrigerated storage.**
2. **Affix the labels supplied by CSL Behring to the top of the box in the available white space [ see example below ].**



3. **Record the information on the label:**
  - The date Vivaglobin<sup>®</sup> was removed from the refrigerated storage.**
  - The new expiry date (5 months from the date the Vivaglobin<sup>®</sup> was removed from refrigerated storage as long as it does not exceed the stamped expiry date from the manufacturer).**
4. **Store Vivaglobin<sup>®</sup> at room temperature (not to exceed +25 °C).**

#### INSTRUCTIONS for ordering the labels

Email us at: [canadacontactus@cslbehring.com](mailto:canadacontactus@cslbehring.com)  
Call Customer Service at: 1-866-773-7721

## CSL Behring

Vivaglobin<sup>®</sup> is indicated for the treatment of patients with primary immune deficiency (PID) who require immune globulin replacement therapy. Vivaglobin<sup>®</sup> is contraindicated in individuals with a history of anaphylactic or severe systemic response to immune globulin preparations, in persons with known antibody against IgA and in patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container<sup>1</sup>. The recommended weekly dose of Vivaglobin<sup>®</sup> is 100 to 200 mg/kg body weight administered subcutaneously. Vivaglobin<sup>®</sup> is supplied as a sterile 16% (160 mg/mL) protein solution containing at least 96% immunoglobulin G (IgG) available in 3ml and 10 ml vials.

Vivaglobin<sup>®</sup> has been shown to be safe and effective in PID patients<sup>2,3</sup>. This cost effective<sup>4</sup> subcutaneous immunoglobulin (SCIG) preparation allows trained patients to administer their therapy at home. Subcutaneous administration of Vivaglobin<sup>®</sup> offers flexibility and freedom of choice to patients who require IG replacement therapy<sup>2,3,5-7</sup>.

CSL Behring offers tools / resources and training for health care professionals who wish to train their PID patients to use Vivaglobin<sup>®</sup> at home. We hope that Vivaglobin<sup>®</sup> will contribute in offering a new solution for some of your patients with PID. For the complete risk / benefit profile as well as for the prescribing information of Vivaglobin<sup>®</sup>, please refer to our currently approved Product Monograph / Prescribing Information, available on our website at [www.cslbehring.ca](http://www.cslbehring.ca).

If you have any questions or require any additional information regarding Vivaglobin<sup>®</sup>, please contact your local Area Manager or the CSL Behring office in Ottawa at 1-866-773-7721.  
Sincerely,



Marie Christine Roberge  
National Immune Globulin Manager  
CSL Behring Canada Inc.

#### References

1. Vivaglobin Product Monograph, July 3, 2009, CSL Behring Canada Inc.
2. Ochs H. D. et al. Safety and efficacy of self-administered immunoglobulin in patients with primary immunodeficiency. *Journal of Clinical Immunology*, 2006; 26: 265-73.
3. Gardulf A. et al. Rapid Subcutaneous IgG Replacement Therapy in Effective and Safe in Children and Adults with Primary Immunodeficiencies – A Prospective, Multi-National Study. *Journal of Clinical Immunology*, 2006; 26: 177-185.
4. Ho C, Membe S, Cimon K, Roifman C, Kanani A, Morrison A. Overview of Subcutaneous Versus Intravenous Immunoglobulin for Primary Immunodeficiencies: Systematic Review and Economic Analysis [Technology overview number 36]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2008. ( note: CADTH is funded by Canadian federal, provincial, and territorial governments).
5. Berger M, et al. Conversion from intravenous to subcutaneous immunoglobulin therapy: relationship between dose, serum trough IgG concentration and infection rate in patients with primary immune deficiency diseases. *J. Allergy Clin Immunol.* 2006;117 (suppl):S109.
6. Gardulf A. Immunoglobulin Treatment for Primary Antibody Deficiencies. *Biodrugs* 2007; 21 (2): 105-116.
7. Berger, Melvin Principles of and Advances in Immunoglobulin Replacement Therapy for Primary Immunodeficiency *Immunology and Allergy Clinics of North America*, 2008; 28: 413-437.