



NATIONAL BIOPRODUCTS INSTITUTE

Association incorporated under Section 21

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Prof. R Eastman
President: Neurological Association of South Africa
E8, Neurology
Groote Schuur Hospital
Cape Town
7925

Dear Prof Eastman

Supply of Polygam

We are aware that some of our customers are experiencing difficulty in sourcing Polygam. This is as a result of a country-wide increase in demand for this product. The trend of increasing usage of IVIG has been reported in the international literature and has been linked with increased off-label usage^{1,2}. Intermittent shortages internationally have necessitated several countries like the UK³, Australia⁴ and Canada⁵ to implement strict control measures on IVIG usage and availability.

As neurological indications form a significant percentage of the total usage of Polygam in SA, we respectfully request NASA to assist us by communicating to your members current restrictions on the availability of Polygam and in particular the critical need for appropriate usage.

In response to the increasing demand for all of our products, NBI has embarked on a 2 to 3 year complex facility upgrade plan that, once complete, will ensure that South African patients continue to have access to sufficient locally manufactured plasma-derived medicines. However, significant portions of this upgrade have to take place whilst routine manufacture continues, which has therefore necessitated longer project timelines. A critical phase in of the upgrade is scheduled to take place in April-May 2011, and for an approximate 8 week period, the plant will be shutdown to facilitate the installation of new plant and equipment. Sufficient stocks of product therefore have to be manufactured prior to April to ensure continuity of supply of these essential products. The key to a successful stock build, is maintaining current product usage over the same period. It is for this aspect of the programme that we request your support.

For the duration of the stock build period, during the shut down and at for least the following 6 months, supplies of Polygam will remain limited. It is therefore of paramount importance that the demand for Polygam remains at current usage levels for the next 12 months. Failure to do so will result in a periodic "out of stock" situation for Polygam.

*NBI is a "not for profit" association
committed to providing
safe, cost effective,
quality products*

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We are therefore appealing to you to encourage your members to prescribe Polygam only for appropriate clinical indications, for which there is a known benefit that has been supported by an evidence-based medical approach, and only at the recommended dosage regimens.

We would be appreciative of any assistance which NASA can provide in this regard and look forward to your feedback.

Yours sincerely



Andrea Muller
Marketing Manager

Pam Larkin
Head: Business Development

Polygam 1 g	Polyvalent human normal immunoglobulin	Z/30.2/367
Polygam 3 g	Polyvalent human normal immunoglobulin	Z/30.2/368
Polygam 6 g	Polyvalent human normal immunoglobulin	Z/30.2/369
Polygam 12 g	Polyvalent human normal immunoglobulin	29/30.2/511

1. Robinson, P *et al.* 2007. Evidence-Based Guidelines on the Use of Intravenous Immune Globulin for Hematologic and Neurologic Conditions. *Transfusion Medicine Reviews*. 21(2), Supplement 1: S3-S8.
2. Feasby, T *et al.* 2007. Guidelines on the Use of Intravenous Immune Globulin for Neurologic Conditions. *Transfusion Medicine Reviews*, 21(2), Supplement 1: S57-S107.
3. www.intravenousimmunoglobulin.org
4. www.nba.gov.au/ivig/
5. Constantine, M *et al.* 2007. Intravenous immunoglobulin utilization in the Canadian Atlantic provinces: a report of the Atlantic Collaborative Intravenous Immune Globulin Utilization Working Group. *Transfusion*. 47: 2072-2080.