

# Pharmacy Bulletin

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## SCARCITY OF IVIG -PLEASE USE JUDICIOUSLY. IVIG PRODUCTS AND USAGE REVIEW IN HCTM

SOME BACKGROUND ON THE SCARCITY OF IVIG...

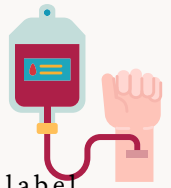
**BACKGROUND:** IVIG has been used in many indications, both FDA approved, and off-label.

IVIG products are derived from human plasma. In the past, major worldwide shortages were noted in the late 1990s. In 2019, the United States suffered insufficient supply of IVIG, resulting in local shortages and rationing. Furthermore, tension on global plasma supply was added on by COVID-19. The unprecedented global crisis resulted in a reduction in donor pool. The high demand coupled with large quantity production challenges has resulted in **increasing global shortages, usage limitations and rationing** of immunoglobulin.

**ISSUE :** Annually, Ministry of Health Malaysia would send approximately 80,000 packs of blood to the Commonwealth Serum Laboratory for fractionation. However, the insufficient collection of immunoglobulin G from the local population resulted in collection from global commercial markets. As such, **scarcity remains the major concern.**

Apart from that, the **increased usage of IVIG for off-label indications** have augmented the shortage problem as they are used for indications which are not supported by strong level of evidence. To add on to the tension of scarcity, there has been a significant price increment of IVIG products in Malaysia as seen in the table below.

	Old Price (2022)	Price / gram	New Price (2023)	Price / gram	Increment
IVIG 2.5 g	RM 517.36	RM 207/g	RM 898	RM 359.2/g	↑ 73.5%
IVIG 5 g	RM 1178.56	RM 236/g	RM 1362.9	RM 272.6/g	↑ 15.5%



As seen from the table above, the price increment is significantly higher with IVIG 2.5g (5%) . Hence IVIG 5g (10%) may be more cost effective with a lower price/gram.

HCTM has obtained a new higher concentration IVIG item **10% (5g/50mL)**, compared to our usual strength of **5% (2.5g/50mL)**. The comparison between both items are as below.

### Comparison between 2 strengths of IVIG available in HCTM

	IV Globulin SN (Green Cross)	Privigen (CSL Behring)
Concentration	2.5g/50mL (5%)	5g/50mL (10%)
Storage	2-8°C. Do not freeze.	2-25°C. (Can be stored in room temperature)
Administration	Initial rate of 0.01-0.02mL/kg/ <b>min</b> for 30 mins. If well tolerated, the rate may be gradually increased to a maximum of 0.1mL/kg/ <b>min</b> .	Initial rate of 0.3mL/kg/ <b>hr</b> for 30 mins. If well tolerated, the rate may be gradually increased to a maximum of 4.8mL/kg/ <b>hr</b> . In patients with immunodeficiency syndrome who have tolerated substitution treatment with Privigen well, the maximum rate may be 7.2mL/kg/ <b>hr</b> .

#### References:

- 1.Privigen Product Information 2. <https://www.privigen.com/common/pdf/privigen-dosing-infusion-rate-brochure.pdf>
- 3.I.V. Globulin SN Inj, Green Cross Product Information 4. Jian Lynn Lee, et. al. Prescribing Practices of IVIG in Tertiary Care Hospitals in Malaysia;2022.

# USAGE REVIEW OF IVIG IN HCTM (APRIL 2022-APRIL 2023)

Based on approved indications by the Drugs and Therapeutics Committee  
(Usage data according to actual dispensed vials recorded by Inpatient Pharmacy)

IVIG USAGE WITH LEVEL OF EVIDENCE				
Indication	Level of evidence; Strength of recommendation <sup>1</sup>	Total patient	Total amount (g)	Average gram/patient
<b>Licensed indication, definitely beneficial</b>				
1. Refractory ITP/ ITP in pregnancy	la (A)	9	1718	191
2. Primary immunodeficiencies	Iib (B)	1	125	125
<b>Off-label, definitely beneficial</b>				
3. Guillain Bare-Syndrome	Ib (B)	15	2010	134
<b>Off-label, probably beneficial</b>				
4. Myasthenia Gravis in Crisis	Ib (B)	5	575	115
<b>Off-label, may provide benefit</b>				
5. Autoimmune Encephalitis	III (C)	2	250	125
6. SLE in severe disease manifestations	III (D)	36	4655	130

Definition of the categorization of evidence, strength of recommendation and beneficial treatment of recommendation.

I	Evidence from at least one large randomized controlled trial of good methodological quality (low potential for bias) or meta-analyses of well-conducted RCTs without heterogeneity
II	Small RCTs or large RCTs with a suspicion of bias (lower methodological quality) or meta-analyses of such trials or of trials with demonstrated heterogeneity
III	Prospective cohort studies
IV	Retrospective cohort studies or case-control studies
V	Studies without control group, case reports, experts' opinions

## Strength of recommendation

A	Strong evidence for efficacy with a substantial clinical benefit, strongly recommended
B	Strong or moderate evidence for efficacy but with a limited clinical benefit, generally recommended
C	Insufficient evidence for efficacy or benefit does not outweigh the risk or the disadvantages (adverse events, costs) optional
D	Moderate evidence against efficacy or for adverse outcome, generally not recommended
E	Strong evidence against efficacy or for adverse outcome, never recommended

## What can we draw from all this information?

In HCTM, IVIG is supplied free for 6 different indications, each with different levels of evidence. Other unapproved, off-label usage will be charged to patients.

Due to increasing demand, limited availability, and frequent interruptions of global plasma supply, please **consider evidence category and strength of recommendation** in clinical decision-making when using IVIG. This will ensure sufficient supply for those with the utmost clinical need.

**REGISTER NOW IN OUR HCTM FORMULARY APP TO VIEW THE PRICES OF NF ITEMS!**

HCTM Formulary App is on...



## References:

1. Lee et al., 2022, Frontiers in pharmacology, 13: 879287. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9218597/>

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