



靜脈注射免疫球蛋白 IVIG

I.V. - Globulin S 50ml



什麼是靜脈注射免疫球蛋白？

What is IVIG (Intravenous Immunoglobulin) -- I.V.-Globulin S 50ml ?

IVIG (I.V. - Globulin S)是由許多捐血者的血漿滙集提取而成，每一批次的 IVIG，約由 10,000 個血漿單位加工處理而成。這些血漿是由本澳自願、無償捐血者捐獻的血液所分離出來的。

I.V. -Globulin S 50ml 含有 2.5 克人類蛋白及 5 克麥芽糖(matose)。IVIG 的活性成份是免疫球蛋白 G，即 IgG。IgG 是正常人體對抗感染而產生的 5 種抗體之一，其餘 4 種其它抗體是 IgM, IgA, IgD, and IgE。每類抗體在人體內均有不同的功能，而 IgG 是長期存在於人體內以保持人體對感染的控制。

I.V. -Globulin S - is a product derived from human blood. The active ingredient is immunoglobulin, IgG. Each **I.V. -Globulin S 50ml** vial contains 2.5 g of IgG and 5 g of maltose. Each batch of I.V.-Globulin S is fractionated from approximately 10,000 blood donations by voluntary blood donors in Macao.

IgG is one of the five classes of immunoglobulin normally produced by our immune system when exposed to foreign antigens. The other immunoglobulins are IgM, IgA, IgD, and IgE. Each one of these classes of Igs are produced in different stages of the immune response and/or are engaged on specific roles in the humoral defense of the body. IgG is the longer lasting antibody.

適應症 Indications

IVIG 的有效性維持 2 周至 3 個月，主要用於治療以下三大類疾病

IVIG's effects last between 2 weeks to 3 months. It is mainly used as treatment in three major categories of illness:

1. 抗體水平低下的免疫缺陷疾病 Immune deficiencies featuring low antibody levels
2. 炎症及自體免疫疾病 Inflammatory and autoimmune diseases
3. 急性感染 Acute infections

美國藥物及食品管理局(FDA)批准下列 6 種疾病可使用 IVIG

The US Food and Drug Administration has approved the use of IVIG for the following 6 conditions :

- a. 先天性免疫力低下 Primary immunodeficiencies
- b. 原發性血小板減少性紫癍 Idiopathic thrombocytopenic purpura
- c. 川崎病 Kawasaki disease
- d. 大于 20 歲並接受了幹細胞移植的病人
Hematopoietic stem cell transplantation in patients older than 20 years
- e. 慢性 B 淋巴細胞白血病 Chronic B-cell lymphocytic leukemia
- f. 兒童 HIV 1 型感染 Pediatric HIV type 1 infection

其它適應症(Off-label Uses) :

- 慢性疲勞綜合症 Chronic fatigue syndrome
- 慢性脫髓鞘多發性神經炎 Chronic inflammatory demyelinating polyneuropathy (CIDP)
- 難治性梭狀芽孢桿菌結腸炎 Clostridium difficile colitis
- 甲狀腺眼病變 Graves' ophthalmopathy
- 肌肉萎縮症 Muscular Dystrophy
- 包涵體肌炎 Inclusion body myositis
- 癌性肌無力綜合症 Lambert-Eaton syndrome
- 紅斑狼瘡症 Lupus erythematosus
- 多源性運動神經病變 Multifocal motor neuropathy
- 多發性硬化症 Multiple sclerosis
- 重症肌無力 Myasthenia gravis
- 新生兒異體抗體免疫性血小板缺乏症 Neonatal alloimmune thrombocytopenia
- Parvovirus B19
- 天皰瘡 Pemphigus
- 輸血後紫癍症 Post-transfusion purpura
- 腎移植後排斥 Renal transplant rejection
- 習慣性流產 Spontaneous Abortion/Miscarriage
- 僵硬人症候群 Stiff person syndrome
- 危重(成年)病人伴嚴重的敗血症和敗血性休克
Severe sepsis and septic shock in critically ill adults
- 中毒性表皮壞死症 Toxic epidermal necrolysis
- 皮肌炎和多發性肌炎 Dermatomyositis and polymyositis
- 格林-巴利綜合症 Guillain-Barré syndrome
- 慢性淋巴細胞性白血病及多發性骨髓瘤，以及各種罕有的免疫球蛋白合成障礙(如 X-染色體連鎖無丙種球蛋白血症，低丙種球蛋白血症)，可注射 IVIG 以維持適當的 IgG 以預防感染。

In chronic lymphocytic leukemia and multiple myeloma, as well as various rare deficiencies



of immunoglobulin synthesis (e.g. X-linked agammaglobulinemia, hypogammaglobulinemia), IVIG is administered to maintain adequate immunoglobulin levels to prevent infections.

劑量及使用 Dosage and Administration

- I.V.-Globulin S 祇作靜脈注射
I.V.-Globulin S should only be administered intravenously.
- 一般劑量：400 mg/kg/day 連續注射 4 天，或以每公斤體重 2 克於 8 至 12 小時輸注。
Common dose regimens, as immunomodulating agent, are 400 mg/kg/day of IVIG for 4 consecutive days or 2 grams/kg as a single day infusion over 8-12 hours.
- 對血清 IgG 水平很低的病人，劑量應為每 3-4 週輸注 I.V.-Globulin S 50ml 300-600 mg/kg 一次，以維持 IgG 水平於 200 mg/dl 以上。
As replacement therapy for patients with low serum IgG concentration, the dosage should be 300-600 mg/kg given once every 3-4 weeks in order to maintain the IgG level above 200 mg/dl.
- 輸注 I.V.- Globulin S 50ml 的起始 30 分鐘，以每分鐘 0.01 ml/kg 速度輸注；之後 30 分鐘，可以每分鐘 0.02 ml/kg 的速度輸注；於第 3 個 30 分鐘，以每分鐘 0.04 ml/kg 的速度輸注；若無任何不良反應，以每分鐘 0.07 ml/kg 的速度輸注。
I.V.-Globulin S should be infused at a rate 0.01 ml/kg per minute in the first 30 minutes. If no adverse reactions occur, the infusion rate can be increased to 0.02 ml/kg per minute for the second 30 minutes and if further tolerated, to 0.04 ml/kg per minute over the third 30 minutes. Thereafter, if no adverse reactions, the infusion can be increased and maintained at 0.07 ml/kg per minute.

併發症及副作用 Complications and side effects

IVIG 併發症包括 Complications of IVIG therapy include :

- 頭痛、發燒及頸硬—無菌性腦膜炎綜合症，緩慢輸注可減輕或此併發症的發生，並可轉介神經科跟進。
- The single most frequent adverse side effect occurring during or following IVIG infusion is headache, that usually is mild and can be easily relieved (or prevented) by analgesics or anti-histamines. Very rarely the patient may develop a meningitis like syndrome - aseptic meningitis syndrome - requiring a thorough neurologic work-up; usually resolves over a few days with no sequela. Can be minimized or prevented by infusing IVIG very slowly.
- 皮炎—手掌及腳掌皮膚剝落
Dermatitis - usually peeling of the skin of the palms and soles

- 由血源污染引起的感染(如 HIV 或病毒性肝炎)，尚有仍未知風險的變異型瘋牛症。
Infection (such as HIV or viral hepatitis) by contaminated blood product; there is also an as yet unknown risk of contracting variant CJD (vCJD).
- 由於 IVIG 的高膠體滲透壓導致液體過量而引起肺水腫
pulmonary edema from fluid overload, due to the high colloid oncotic pressure of IVIG
- 過敏/超敏反應 allergic/anaphylactic reactions
- 由 IVIG 內含如肝炎抗體直接引致的損害
damage such as hepatitis caused directly by antibodies contained in the pooled IVIG
- 急性腎衰竭 acute renal failure
- 靜脈栓塞 venous thrombosis
- 低血糖血症：**I.V. -Globulin S** 內所含的麥芽糖可干擾一些血糖檢測，可致高估了血糖結果。若以此血糖檢測作參考而治療，將致病人低血糖。麥芽糖在 IVIG 中作為穩定劑 (10 克/100 毫升) 的功能以維持產品的等張性。
Hypoglycaemia: The maltose present in **I.V. -Globulin S** may interfere with some blood glucose measurements, resulting in the overestimation of blood glucose results. If this glucose measurement is used to guide treatment hypoglycaemia may occur. Maltose is added as a stabilizer (10gm/100ml) and contributes to the isotonicity of the product.

IVIG 注意事項 IVIG notes

- 輸注 IVIG 其實祇給予了 IgG。而外週組織如眼睛、肺臟、腸道及泌尿道主要是由 IgA 抗體來保護的，因此，輸注 IVIG 不能完全保護外週組織受侵。

IVIG is an infusion of IgG antibodies only. Therefore, peripheral tissues that are defended mainly by IgA antibodies, such as the eyes, lungs, gut and urinary tract are not fully protected by the IVIG treatment.

- 須於輸注 IVIG 前為接受高劑量 IVIG (>0.4 克/公斤 每 4 星期) 的病人，確定 ABO 血型，以及於輸注後數天，定期檢測其血紅蛋白水平，以確定有無具臨床意義的溶血。

Patients receiving high dose IVIG (>0.4 g/kg every 4 weeks) should have a pre-infusion ABO blood group determined and have their haemoglobin monitored in the days following therapy for evidence of clinically significant haemolysis.

- IVIG 的副作用多與輸注速度有關，最常發生於輸注首 1 小時內。建議在輸注期間定時監測病人的生命體征及一般情況。

Reactions to IVIG tend to be related to the infusion rate and are most likely to occur during the first hour of the infusion. It is recommended that the patient's vital signs and general status are monitored regularly throughout the infusion.

- 如果副作用再次發生，建議減慢輸注的速度及劑量。

In case of recurring side effects, it is recommended to slow the pace of the IVIG



administration and to reduce the dosage.

申請方法 How to request?

填妥 SS-Mod. 007 表格，或以 UDD 處方系統申請，並送交仁伯爵綜合醫院藥房處理。

Fill in a SS-Mod. 007 form or an UDD prescription and send it to Divisão de Farmácia of CHCSJ for processing.