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人免疫球蛋白说明书

请仔细阅读说明书并在医师指导下使用

警 示

因原料来自人血，虽然对原料血浆进行了相关病原体的筛查，并在生产工艺中加入了去除和灭活病毒的措施，但理论上仍存在传播某些已知和未知病原体的潜在风险，临床使用时应权衡利弊。

【药品名称】

通用名称：人免疫球蛋白
英文名称：Human Immunoglobulin
汉语拼音：Ren Mianyiqiudanbai

【成份】

本品系由健康人血浆，经低温乙醇蛋白分离法分离纯化，并经病毒去除和灭活处理制成。含适宜稳定剂，不含防腐剂 and 抗生素。

本品使用的辅料：甘氨酸、氯化钠。

【性状】本品应为无色或淡黄色澄明液体，可带乳光，不应出现浑浊。

【适应症】主要用于预防麻疹，若与抗生素合并使用，可提高对某些严重细菌和病毒感染的疗效。

【规格】150mg/瓶（10%，1.5ml），300mg/瓶（10%，3ml）。

【用法用量】

用 法：仅限于肌肉注射，不得用于静脉输注。

用 量：预防麻疹：为预防发病或减轻症状，可在与麻疹患者接触7日内按每kg体重注射0.05~0.15ml，5岁以下儿童注射1.5~3.0ml，6岁以上儿童最大注射量不超过6ml。一次注射预防效果通常为2~4周。

【不良反应】

尚待积累规范系统的不良反应监测资料。少数人会出现注射部位红肿、疼痛反应，偶尔会出现发热、皮疹或荨麻疹，无需特殊处理，可自行恢复。

【禁 忌】

1. 对免疫球蛋白过敏或有其他严重过敏史者。

2. 对IgA抗体的选择性IgA缺乏者。

【注意事项】

1. 本品出现混浊，有摇不散的沉淀、异物或玻璃有裂纹、过期失效，均不可使用。

2. 开瓶后应一次注射完毕，不得分次使用。

3. 运输及贮存过程中严禁冻结。

【孕妇及哺乳期妇女用药】尚不明确。

【儿童用药】见【用法用量】项。

【老年用药】尚不明确。

【药物相互作用】应单独使用。

【药物过量】尚不明确。

【药理毒理】

药理作用：注射免疫球蛋白是一种被动免疫疗法。它是把免疫球蛋白内含有的大量抗体输给受者，使之从低或无免疫状态很快达到暂时免疫保护状态。由于抗体与抗原相互作用起到直接中和毒素与杀死细菌和病毒的作用，因此免疫球蛋白制品对预防细菌、病毒性感染有一定的作用。

毒理研究：尚不明确。

【药代动力学】据文献报道，人免疫球蛋白的生物半衰期为16~24天。

【贮 藏】于2~8℃避光保存和运输。

【包 装】包装材料和容器：西林瓶；包装规格：1瓶/盒。

【有 效 期】36个月。

【执行标准】YBS05182019

【批准文号】国药准字S19993060（150mg/瓶（10%，1.5ml））、国药准字S19993061（300mg/瓶（10%，3ml））

【药品上市许可持有人】深圳市卫光生物制品股份有限公司

【地 址】深圳市光明新区光明街道光侨大道3402号

【生产企业】企业名称：深圳市卫光生物制品股份有限公司

生产地址：深圳市光明新区光明街道光侨大道3402号

邮政编码：518107

电话：(0755) 27409800 27404445 传真：(0755) 27404445

不良反应专线：(0755) 27409223

网址：<http://www.szwg.com> E-mail：szwg@szwg.com

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Human Immunoglobulin Instructions

Please read through the instructions and follow doctor's advice.

Warning

The raw material of the product is from human blood plasma. Although it's screened for related infectious agents and simultaneously virus removal and inactivation procedure are included in the manufacturing process, such products may still potentially carry along some known or unknown infectious agents, so one must balance risk versus benefit in clinical.

[Drug Name]
Human Immunoglobulin
Ren Mianyiqiudanbai

[Composition]
The product is prepared from healthy person plasma and processed through the Cold Ethanol Handicraft with eliminating and deactivating the virus. It contains a proper stabilizer, and contains no antibiotics or preservative.
Adjuvant: Chlorhydric acid, Sodium chloride.

[Description]
The product should be colorless or pale yellow clear liquid, which may be opalescent, and should not be turbid.

[Indications]
The product is intended to prevent measles. It has enhanced effect to prevent infection of some severe bacteria and viruses if used in combination with antibiotics.

[Specification] 150mg/bottle(10%, 1.5ml), 300mg/bottle(10%, 3ml).

[Administrations and Dosage]

Usage: only for intramuscular injection, and intravenous infusion is not allowed.
Dosage: Preventing from measles: To prevent the disease from attacking or alleviate the symptom, a portion of 0.05~0.15ml per kg shall be injected for people who have contacted a measles patient shall be injected within seven days; 1.5~3.0ml for children below the age of five; not more than 6ml for children above the age of six. An injection will take effect within two to four weeks.

[Adverse Reactions]

Normative and systematic adverse reactions monitoring data have yet to be accumulated. Injection site swelling and pain reaction occur in a small number of cases. Fever, rash and hives appear in rare cases. These symptoms are usually disappear without any special treatment.

[Contraindications]

1. People who are allergic to human immunoglobulin or have a record of any other severe allergy;
2. People with IgA antibody in selective IgA deficiency.

[Precautions]

1. The product shall not be used if the liquid is turbid, there is stubborn sediment, particulate matters, a flaw in the glass, or the product becomes invalid.
2. Use the product one-off after opening, and more than one time of usage are not allowed;
3. No freezing during transportation or storage.

[Pregnancy and Nursing Mothers Use] Uncertain

[Pediatric Use] see [Dosage and Usage]

[Geriatric Use] Uncertain

[Drug Interactions] Uncertain

[Overdose] Uncertain

[Pharmacology and Toxicology]

Pharmacological action: Injecting immunoglobulin falls into a kind of passive immunotherapy, where massive antibodies contained in the immunoglobulin are infused to the receiver so that the body will be upgraded from low or non immunity to the temporary immune protection quickly. As antibodies interact with antigens to neutralize toxins and kill bacteria and viruses, immunoglobulin can prevent the body from the infection of bacteria and viruses.

Toxicology: Uncertain

[Pharmacokinetics] According to written records, the biological half-life period of human immunoglobulin is 16-24 days.

[Storage] Avoiding from the light at 2~8°C

[Package] Packing material and container: Vial; Packing Specification: 1 bottle/case.

[Validity] 36 months.

[Executive Standard] YBS05182019

[Number of Documents of Approval] GYZZ No. S19993060 [150mg/bottle(10%, 1.5ml)], GYZZ No. S19993061 [300mg/bottle(10%, 3ml)]

[Marketing Authorization Holder] Shenzhen Weiguang Biological Products CO., LTD.

[Address] No.3402 Guangqiao Avenue, Guangming Street, Guangming New Area, ShenZhen

[Producer]

Company name: Shenzhen Weiguang Biological Products CO., LTD.
Factory address: No.3402 Guangqiao Avenue, Guangming Street, Guangming New Area, ShenZhen

Postcode: 518107

Tel: (0755) 27409800 27404445 Fax: (0755) 27404445

Adverse reaction line: (0755) 27409223

Website: <http://www.szwg.com> E-mail: szwg@szwg.com