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2015年11月22日
2019年02月19日
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2025年06月19日

静注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

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: 静注人免疫球蛋白

英文名称: Human Immunoglobulin for Intravenous Injection

汉语拼音: Jingzhu Ren Mianyiqiudanbai

【成份】

主要组成成份: 本品蛋白质中95%以上为免疫球蛋白。本品来源于健康人血浆, 经低pH释放和除病毒膜过滤两步灭活/去除病毒处理。

辅料: 山梨醇

【性状】

无色或淡黄色澄明液体, 可带轻微乳光, 不应出现浑浊。

【适应症】

- 原发性免疫球蛋白缺乏症, 如X连锁低免疫球蛋白血症, 常见变异型免疫缺陷病, 免疫球蛋白G亚型缺陷病等。
- 继发性免疫球蛋白缺陷病, 如重症感染, 新生儿败血症等。
- 自身免疫性疾病, 如原发性血小板减少性紫癜, 川崎病。

【规格】

1g/瓶(5%, 20ml); 2.5g/瓶(5%, 50ml); 5g/瓶(5%, 100ml); 10g/瓶(5%, 200ml)。

【用法用量】

用法: 静滴注或以5%葡萄糖注射液稀释1~2倍作静脉滴注, 开始滴注速度为1.0ml/分(约20滴/分), 持续15分钟后若无不良反应, 可逐渐加快速度, 最快滴注速度不得超过3.0ml/分(约60滴/分)。

用量: 遵医嘱。推荐剂量:

- 原发性免疫球蛋白缺乏或低下症: 首次剂量: 400mg/kg体重; 维持剂量: 200~400mg/kg体重, 给药间隔时间视病人血清IgG水平和病情而定, 一般每月一次。
- 原发性血小板减少性紫癜: 每日400mg/kg体重, 连续5日。维持剂量每次400mg/kg体重, 间隔时间视血小板计数和病情而定, 一般每周一次。
- 重症感染: 每日200~300mg/kg体重, 连续2~3日。



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4. 川崎病: 发病10日内应用, 儿童治疗剂量2.0g/kg体重, 一次输注。

【不良反应】

一般无不良反应, 极个别病人在输注时出现一过性头痛、心慌、恶心等不良反应, 可能与输注速度过快或个体差异有关。上述反应大多轻微且常发生在输液开始一小时内, 因此建议在输注的全过程定期观察病人的总体情况和生命特征, 必要时减慢或暂停输注, 一般无需特殊处理即可自行恢复。个别病人可在输注结束后发生上述反应, 一般在24小时内均可自行恢复。

1. 国外临床试验

同类的国外上市产品在超过5%的临床试验受试者中观察到以下常见不良反应: 头痛、寒战、发热、疼痛、乏力、背痛、恶心、呕吐、腹痛、腹泻、输液部位反应、皮疹、瘙痒、荨麻疹、高血压、低血压、心动过速等。

2. 国内上市后监测

本品及同类的国内上市产品监测到如下不良反应/事件, 由于这些不良反应/事件是在无法确定总数的人群中自发报告的, 因此不能准确估算其发生率:

- (1) 全身性损害: 畏寒、高热、胸痛、不适、苍白、乏力、眶周水肿、水肿、全身酸痛等。
- (2) 皮肤及其附件损害: 斑丘疹、红斑性皮疹、局限性皮肤反应、表皮松懈、多发性红斑、皮炎(如大疱性皮炎)、出汗增加等。
- (3) 免疫功能紊乱和感染: 过敏反应、过敏样反应、输液反应、过敏性休克等。
- (4) 心血管系统损害: 紫绀、心悸、高血压、心律失常等。
- (5) 神经系统损害: 头晕、昏迷、意识丧失、震颤、肌肉不自主收缩、感觉减退等。
- (6) 呼吸系统损害: 呼吸困难、呼吸急促、呼吸暂停、喘息、喉头水肿、呼吸功能不全、输血相关急性肺损伤、低氧血症等。
- (7) 血管损害和出血性障碍: 潮红、静脉炎等。
- (8) 精神障碍: 激越、精神障碍、嗜睡等。
- (9) 血液系统损害: 白细胞减少、中性粒细胞减少、粒细胞缺乏等。

3. 国外上市后监测

同类的国外上市产品还监测到如下不良反应/事件, 由于这些不良反应/事件是在无法确定总数的人群中自发报告的, 因此不能准确估算其发生率:

- (1) 皮肤及其附件损害: 史蒂文斯-约翰逊综合征等。
- (2) 神经系统损害: 癫痫发作、无菌性脑膜炎等。
- (3) 呼吸系统损害: 急性呼吸窘迫综合征、肺水肿、支气管痉挛等。
- (4) 血管损害和出血性障碍: 血栓形成等。
- (5) 血液系统损害: 血浆黏度增加、溶血反应等。
- (6) 泌尿系统损害: 肾功能损害等。

【禁忌】

1. 对人免疫球蛋白过敏或有其他严重过敏史者。
2. 有抗IgA抗体的选择性IgA缺乏者。

【注意事项】

1. 本品专供静脉输注用。
2. 如需要, 可以用5%葡萄糖注射液稀释本品, 但糖尿病患者应慎用。
3. 药液呈现混浊、沉淀、异物或瓶子有裂纹、过期失效, 不得使用。
4. 本品开启后, 应一次输注完毕, 不得分次或给第二人输用。
5. 有严重酸碱代谢紊乱的病人应慎用。
6. 监测急性肾功能衰竭患者的肾功能, 包括尿素氮、肌酐和尿量。对于肾功能不全或衰竭的患者, 要以最小的速度输注。易感患者使用本品可能引起肾功能异常。使用含蔗糖的产品, 更易引起患者肾功能异常和急性肾功能衰竭。本品不含蔗糖。
7. 可能发生血栓性事件。监测有血栓形成事件已知危险因素的患者; 对有高粘血症风险患者的血液粘度进行基线评估。对于有血栓形成风险的患者, 要在最小剂量下缓慢输注。
8. 可能发生无菌性脑膜炎综合征, 特别是在高剂量或快速输注时。
9. 可能发生溶血性贫血。监测溶血和溶血性贫血患者的临床体征和症状。

【孕妇及哺乳期妇女用药】

对孕妇或可能怀孕妇女的用药应慎重, 如有必要应用时, 应在医师指导和严密观察下使用。

【儿童用药】

未进行此项实验。

【老年用药】

未进行该项试验研究, 且无系统可靠的参考文献。在65岁以上的患者中, 一般情况下, 不超过推荐剂量, 缓慢输注。



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Date Approved: Apr. 02, 2007 Oct. 01, 2025

Date Revised: Dec. 09, 2010
Nov. 22, 2015
Feb. 19, 2019
Dec. 30, 2020
Jun. 19, 2025

GAMMARAAS® - Human Immunoglobulin for Intravenous Injection

Read the Package Insert Carefully and under the Instruction of Physician

WARNING

This product is human-plasma-derived. Although the screening and testing measures of infectious agents and viral removal and inactivation are added in the manufacture process, theoretically, there is still potential risk of transmitting some known and even unknown infectious agents. The risk-benefit analysis should be taken before administration.

Product name

Generic Name: Human Immunoglobulin for Intravenous Injection.

Ingredients

Active Ingredients: Over 95% of protein in GAMMARAAS® is immunoglobulin. Derived from human plasma of healthy donors. GAMMARAAS® has been treated with low pH method to inactivate virus, and nanofiltration to remove virus.

Excipients: sorbitol

Characters

GAMMARAAS® is a colourless or pale yellow liquid and clear or slightly opalescent solution, but without turbidity.

Indications

1. Primary immunodeficiency, such as X-linked hypogammaglobulinemia, common variable immunodeficiency, selective IgG subclass deficiency.
2. Secondary immunodeficiency, such as severe infections, hemato-sepsis of newborns.
3. Autoimmune diseases, such as idiopathic thrombocytopenic purpura (ITP), Kawasaki Syndrome (KS).

Specifications

1g per vial (5%, 20ml); 2.5g per vial (5%, 50ml);
5g per vial (5%, 100ml); 10g per vial (5%, 200ml)

Dosage and administration

Administration: GAMMARAAS® should be administered intravenously or infused after it is diluted 1-2 times with 5% glucose injection. For the infusion of GAMMARAAS®, the initial rate should be 1.0ml/minute (approximate 20 drops/minute). If well tolerated for the first 15 minutes, the infusion rate may be gradually increased to a maximum rate of 3.0 ml/min (approximate 60 drops/min).

Dosage: the physician should prescribe GAMMARAAS®. The recommended dosage is the following:

1. Primary immunodeficiency: Starting dosage: 400mg/kg (body weight); maintenance dosage: 200-400mg/kg (body weight). The dosage interval depends on patient's condition and serum IgG level, in general once a month is recommended.
2. Idiopathic thrombocytopenic purpura (ITP): 400mg/kg (body weight)/day for 5 days. Maintenance dosage: 400mg/kg (body weight) per infusion. The dosage interval depends on patient's condition and platelet count, in general once a week is recommended.
3. Severe infections: 200-300mg/kg (body weight)/day for 2 to 3 days.
4. Kawasaki syndrome: administrate within 10 days of the course of Kawasaki syndrome, paediatric dose 2.0g/kg (body weight), may be given as a single infusion.

Adverse reactions

In general, the incidence of adverse reaction is rare. Symptoms reported include headache, palpitation, and nausea. These reactions are often related to the infusion rate and individual difference. Reactions are often mild and occur within one hour after the infusion, so it is recommended that general conditions and vital signs of the patients should be monitored periodically during the course of the infusion. The infusion should be slowed down or interrupted if necessary, and patients usually can recover by themselves without specific treatments. Individual patients may have the above adverse reactions after the infusion, and they usually also can recover by themselves within 24 hours.

1. Clinical trial data abroad

The following common adverse reactions were observed in more than 5% of the clinical trial subjects after using the same type of products authorized abroad: headache, chills, fever, pain, fatigue, back pain, nausea, vomiting, abdominal pain, diarrhea, infusion site reaction, rash, pruritus, urticaria, hypertension, hypotension, tachycardia, etc.

2. Post-marketing surveillance in China

The following adverse reactions/events have been detected in this product and the same type of products authorized in China. These adverse reactions/events are from spontaneously reporting, and occurrence frequencies cannot be evaluated accurately due to the undetermined total population base:

- (1) Systemic damage: chills, hyperpyrexia, chest pain, discomfort, pallor, fatigue, periorbital edema, edema, body pain, etc.
- (2) Damage to skin and its accessories: maculopapule, erythematous rash, localized skin reaction, epidermolysis, multiple erythematous lesions, dermatitis (such as bullous dermatitis), increased sweating, etc.
- (3) Immune dysfunction and infection: anaphylaxis, allergic reactions, infusion related reaction, anaphylactic shock, etc.
- (4) Damage to cardiovascular system: cyanosis, palpitation, hypertension, arrhythmia, etc.
- (5) Damage to nervous system: dizziness, coma, loss of consciousness, tremor, involuntary muscle contraction, hypoesthesia, etc.
- (6) Damage to respiratory system: dyspnea, tachypnea, apnea, gasp, laryngeal edema, respiratory insufficiency, transfusion-related acute lung injury, hypoxemia, etc.
- (7) Vascular lesion, bleeding and coagulation dysfunction: flushing, phlebitis, etc.
- (8) Mental disorder: agitation, psychosis, lethargy, etc.

- (9) Damage to blood system: leukopenia, neutropenia, granulocytopenia, etc.
3. Post-marketing surveillance abroad

The following adverse reactions/events were also detected in the same type products which are authorized abroad. These adverse reactions/events are from spontaneously reporting, and occurrence frequencies cannot be evaluated accurately due to the undetermined total population base:

- (1) Damage to skin and its accessories: Stevens - Johnson syndrome, etc.
- (2) Damage to nervous system: seizures, aseptic meningitis, etc.
- (3) Damage to respiratory system: acute respiratory distress syndrome, pulmonary edema, bronchospasm, etc.
- (4) Vascular lesion, bleeding and coagulation dysfunction: thrombosis, etc.
- (5) Damage to blood system: increased plasma viscosity, hemolytic reaction, etc.

- (6) Damage to urinary system, renal function damage.

Contraindications

1. GAMMARAAS® is contraindicated in individuals who have an anaphylactic or severe systemic reaction to immunoglobulin or have a history of other severe allergic reactions.
2. GAMMARAAS® is contraindicated in individuals with selective IgA deficiencies who have developed antibody against IgA.

Precautions

1. GAMMARAAS® should be administered intravenously only.
2. If necessary, GAMMARAAS® may be diluted with 5% glucose injection. However, caution should be taken in diabetic patients.
3. GAMMARAAS® cannot be used if the solution appears to be turbid or contains any deposit or foreign particles, or there is any crack on the bottle, or the product has been expired.
4. Once the container has been opened, the content should be used in a single infusion. Any unused product cannot be used for another infusion or by another patient.
5. Caution should be taken in patients with severe acid-alkali metabolic disorder.
6. Monitoring renal function in patients with acute renal failure, including blood urea nitrogen, serum creatinine and urine volume. For the patients with renal insufficiency or failure, IVIG products should be administrated at minimum rate of infusion. This product may cause renal dysfunction in susceptible patients. Renal dysfunction and acute renal failure are more likely to occur in patients at risk when using products containing sucrose as an excipient. GAMMARAAS® does not contain sucrose.
7. Thrombotic events may occur. Monitor patients with pre-existing risk factors for thrombotic events, and carry out baseline assessment of blood viscosity in patients at risk for hyperviscosity. As for the patients at risk of thrombosis, the infusion should be performed slowly at minimal doses.
8. Aseptic meningitis syndrome may occur, especially at high dosage or rapid infusion.
9. Hemolytic anemia may occur. Clinical signs and symptoms of hemolysis and hemolytic anemia should be monitored.



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【药物相互作用】

本品应单独输注, 不得与其他药物混合输用。

【药物过量】

未进行此项实验且无可靠参考文献。

【药理毒理】

药理作用: 本品含有广谱抗病毒、细菌或其他病原体的IgG抗体, 另外免疫球蛋白的独特型和抗独特型抗体能形成复杂的免疫网络, 所以具有免疫替代和免疫调节的双重治疗作用。经静脉输注后, 能迅速提高受者血液中的IgG水平, 增强机体的抗感染能力和免疫调节功能。

毒理研究: 未进行此项实验且无可靠参考文献。

【药代动力学】

未进行此项实验且无可靠参考文献。

【贮藏】

于2~8°C避光保存和运输, 严禁冻结。

【包装】

玻璃瓶装, 每盒1瓶。

【有效期】

36个月

【执行标准】

1g/瓶(5%, 20ml): 《中华人民共和国药典》2025年版三部、药品补充申请批准通知书(编号: 2022B02219);
2.5g/瓶(5%, 50ml): 《中华人民共和国药典》2025年版三部、药品补充申请批准通知书(编号: 2021B01794);
5g/瓶(5%, 100ml): 《中华人民共和国药典》2025年版三部、药品补充申请批准通知书(编号: 2021B03372);
10g/瓶(5%, 200ml): 《中华人民共和国药典》2025年版三部、药品补充申请批准通知书(编号: 2022B02218)。

【批准文号】

1g/瓶(5%, 20ml): 国药准字S10980060;
2.5g/瓶(5%, 50ml): 国药准字S10980061;
5g/瓶(5%, 100ml): 国药准字S20013054;
10g/瓶(5%, 200ml): 国药准字S20103006。

【上市许可持有人】

上市许可持有人名称: 上海莱士血液制品股份有限公司

上市许可持有人地址: 上海市奉贤区望园路2009号

邮政编码: 201401

【生产企业】

企业名称: 上海莱士血液制品股份有限公司

生产地址: 上海市奉贤区望园路2009号

邮政编码: 201401

电话: 021-22130888 传真: 021-37515875

网址: http://www.raas-corp.com

Pregnancy and lactation

Caution should be taken with pregnant women and women who are probably pregnant. When necessary, the administration of the product should be under physicians' instruction and closely monitored.

Pediatric

No relevant trials of GAMMARAAS® were performed.

Geriatric

There is no specific clinical investigation in the geriatric population and no relevant literature references are available. For patients over 65 years old, the posology should not exceed the recommended dose and the infusion should be performed at a slow rate.

Drug interactions

GAMMARAAS® should be infused via a separate intravenous line, and cannot be infused with other drugs.

Overdose

No relevant trials of GAMMARAAS® were performed and no relevant literature references are available.

Pharmacology and toxicology

Pharmacology: GAMMARAAS® contains a broad spectrum of IgG antibodies against bacterial, viral agents, and other pathogens. The idiotype and the anti-idiotype of immunoglobulin constitute a complex immune network. So immunoglobulin has duplex therapeutic functions, namely immune replacement and immune adjustment. The IgG level in plasma increases immediately after intravenous infusion, which enhances the capabilities of anti-infection and immune adjustment of human body.

Toxicology: The toxicology studies were not conducted and no relevant literature references are available.

Pharmacokinetics

The studies were not performed and no relevant literature references are available.

Storage and shipping

Store and ship at 2-8°C, protected from light. Do not freeze.

Package

Glass bottle, one vial per package.

Shelf life

36 months.

Executed standard

1g per vial (5%, 20ml): Approval Letter No. 2022B02219, Pharmacopoeia of the People's Republic of China(2025), volume III;
2.5g per vial(5%, 50ml): Approval Letter No. 2021B01794, Pharmacopoeia of the People's Republic of China(2025), volume III;
5g per vial(5%, 100ml): Approval Letter No. 2021B03372, Pharmacopoeia of the People's Republic of China(2025), volume III;
10g per vial(5%, 200ml): Approval Letter No. 2022B02218, Pharmacopoeia of the People's Republic of China(2025), volume III.

Product License No.

1g per vial (5%, 20ml): 国药准字S10980060;
2.5g per vial (5%, 50ml): 国药准字S10980061;

5g per vial (5%, 100ml): 国药准字S20013054;
10g per vial (5%, 200ml): 国药准字S20103006.

Marketing Authorization Holder

Name: Shanghai RAAS Blood Products Co., Ltd.

Address: No. 2009 Wang Yuan Road, Fengxian, Shanghai, P.R.China

Zip code: 201401

Manufacturer

Name: Shanghai RAAS Blood Products Co., Ltd.

Address: No. 2009 Wang Yuan Road, Fengxian, Shanghai, P.R.China

Zip code: 201401

Tel: (86-21)-22130888 Fax: (86-21)-37515875

Web Site: http://www.raas-corp.com