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2025年10月01日

CS3301

人凝血因子Ⅷ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：人凝血因子Ⅷ
英文名称：Human Coagulation Factor Ⅷ
汉语拼音：Ren Ningxueyinzi Ⅷ
【成份】
主要组成成份：人凝血因子Ⅷ。本品来源于健康人血浆，经过 TNBP 和 Tween 80 混合物（S/D）处理以及100℃ 30分钟加热处理两步病毒灭活。
辅料：枸橼酸钠，甘氨酸，聚山梨酯80，氯化钙，氢氧化钠，盐酸
【性状】
乳白色疏松体，复溶后溶液应为无色澄明液体，可带轻微乳光。
【适应症】
本品对缺乏人凝血因子Ⅷ所致的凝血机能障碍具有纠正作用，主要用于防治甲型血友病和获得性凝血因子Ⅷ缺乏而致的出血症状及这类病人的手术出血治疗。
【规格】
每瓶含人凝血因子Ⅷ100IU。复溶后体积为10ml/瓶。
每瓶含人凝血因子Ⅷ200IU。复溶后体积为10ml/瓶。
每瓶含人凝血因子Ⅷ250IU。复溶后体积为10ml/瓶。
每瓶含人凝血因子Ⅷ300IU。复溶后体积为10ml/瓶。
每瓶含人凝血因子Ⅷ400IU。复溶后体积为10ml/瓶。
每瓶含人凝血因子Ⅷ500IU。复溶后体积为10ml/瓶。
每瓶含人凝血因子Ⅷ1000IU。复溶后体积为10ml/瓶。
【用法用量】
用法：本品专供静脉输注，应在临床医师的严格监督下使用。用前应先以25～37℃灭菌注射用水按瓶签的标示量注入瓶内（制品刚从冰箱取出或在冬季温度较低时应特别注意使制品温度升高到25～37℃，然后进行溶解，否则易析出沉淀），轻轻摇动，使制品完全溶解（注意勿使产生泡沫），然后用带有滤网装置的输血器进行静脉滴注，滴注速度一般以每分钟60滴左右为宜。制品溶解后应立即使用，并在1小时内输完，不得放置。
用量：给药剂量必须参照体重、是否存在抑制物，出血的严重程度等因素。下列公式可用于计算剂量：
所需因子Ⅷ单位（IU）/次＝0.5×患者体重（kg）×需提升的因子Ⅷ活性水平（正常的%）
例如：所需因子Ⅷ单位（IU）/次＝0.5×50（kg）×30（%）＝750IU

一般推荐剂量如下：
1. 轻度至中度出血：单一剂量10～15 IU/kg体重，将因子Ⅷ水平提高到正常人水平的20～30%。
2. 较严重出血或小手术：需将因子Ⅷ水平提高到正常人水平的30～50%，通常首次剂量15～25 IU/kg体重。如需要，每隔8～12小时给予维持剂量10～15 IU/kg体重。
3. 大出血：危及生命的出血如口腔、泌尿系统及中枢神经系统出血或重要器官如颈、喉、腹膜后，髂腰肌附近的出血：首次剂量40 IU/kg体重，然后每隔8～12小时给予维持剂量20～25 IU/kg体重。疗程需由医生决定。
4. 手术：只有当凝血因子Ⅷ抑制物水平无异常增高时，方可考虑择期手术。手术开始时血液中因子Ⅷ浓度需达到正常人水平的60～120%。通常在术前按30～40IU/kg体重给药。术后4天内因子Ⅷ最低应保持在正常人水平的60%，接下去的4天减至40%。
5. 获得性因子Ⅷ抑制物增多症：应给予大剂量的凝血因子Ⅷ，一般超过治疗血友病患者所需剂量一倍以上。
【不良反应】
不良反应包括寒颤、恶心、头晕或头痛，这些症状通常是暂时的。有可能发生过敏反应。
【禁忌】
对本品过敏者禁用。
【注意事项】
1. 大量反复输入本品时，应注意出现过敏反应、溶血反应及肺水肿的可能性，对有心脏病的患者尤应注意。
2. 本品溶解后，一般为澄明略带乳光的溶液，允许微量细小蛋白颗粒存在。用于输注的输血器必需带有滤网装置。但如发现有大块不溶物时，则不可使用。
3. 本品对于因缺乏因子Ⅸ所致的乙型血友病，或因缺乏因子Ⅺ所致的丙型血友病均无疗效，故在用前应确诊患者系属因子Ⅷ缺乏，方可使用本品。
4. 本品不得用于静脉以外的注射途径。
5. 本品被溶解后应立即使用，并在一小时内用完。未用完部分必须弃去。
6. 请勿使用超过有效期限的产品。如在配制时发现制剂瓶已失去真空度，不得使用。
【孕妇及哺乳期妇女用药】
目前尚无凝血因子Ⅷ对动物生殖影响的研究，也不清楚因子Ⅷ用于孕妇是否会对胎儿造成损害或影响生育能力。人凝血因子Ⅷ制剂仅在十分必须的情况下才给孕妇使用。
【儿童用药】
应慎重。
【老年用药】
未进行此项实验且无可靠参考文献。
【药物相互作用】
应单独输注，不得与其他药物合用。

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【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：在内源性血凝过程中，凝血因子Ⅷ作为一辅因子，在Ca^{2+}和磷脂存在下，与激活的凝血因子Ⅸ参与凝血因子Ⅹ的激活凝血酶原，形成凝血酶，从而使凝血过程正常进行。输用每公斤体重1个单位的人凝血因子Ⅷ，可使循环血液中的因子Ⅷ水平增加2%～2.5%。
毒理研究：未进行此项实验且无可靠参考文献。
【药代动力学】
生物半衰期为8～12小时。
【贮藏】
于2-8℃避光保存和运输。
【包装】
玻璃瓶装，每盒1瓶。
【有效期】
24个月
【执行标准】
100IU：《中华人民共和国药典》2025年版三部及药品补充申请批件（批件号：2017B02070）；
200IU：《中华人民共和国药典》2025年版三部及药品补充申请批件（批件号：2017B02007）；
250IU：《中华人民共和国药典》2025年版三部及药品补充申请批件（批件号：2017B02008）；
300IU：《中华人民共和国药典》2025年版三部及药品补充申请批件（批件号：2017B02067）；
400IU：《中华人民共和国药典》2025年版三部及药品补充申请批件（批件号：2017B02069）；
500IU：《中华人民共和国药典》2025年版三部及药品补充申请批件（批件号：2017B02068）；
1000IU：《中华人民共和国药典》2025年版三部及药品补充申请批件（批件号：2017B02066）。
【批准文号】
100IU：国药准字S10950029； 200IU：国药准字S10950028；
250IU：国药准字S10980062； 300IU：国药准字S10950030；
400IU：国药准字S10950037； 500IU：国药准字S10980063；
1000IU：国药准字S10980064。
【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
上海莱士凝血因子免费咨询电话：400-820-1126
网址：http://www.raas-corp.com

Date Approved: Apr. 02, 2007
Date Revised: May. 17, 2017 Jun.01, 2017 Dec. 30, 2020 Oct. 01, 2025

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HEMORAAS® -Human Coagulation Factor VIII

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 added in the manufacture process, theoretically, there is still potential risk in the transmission of some known and even unknown infectious agents. The risk-benefit analysis should be taken before administration.

Product name
Generic Name: Human Coagulation Factor Ⅷ
Ingredients
Active Ingredients: Human Coagulation FactorⅧ. Derived from human plasma of healthy donors, HEMORAAS® has been treated with a mixture of tri-n-butyl-phosphate (TNBP) and polysorbate 80 (Tween 80), and the final product has been virus inactivated by Dry Heat treatment at 100℃ for 30 minutes.
Excipients: sodium citrate, glycine, tween 80, calcium chloride, sodium hydroxide, hydrochloric acid
Characters
HEMORAAS® is a kind of white loose powder. After reconstitution, the solution is clear or with slight opalescence.
Indications
HEMORAAS® is indicated for correcting the disorder of coagulation due to deficiency of human coagulation Factor Ⅷ, mainly for prevention and control of bleeding in patients with hemophilia A or acquired Factor Ⅷ deficiency, and for treatment of bleeding caused by operation of these patients.
Specifications
100IU/vial. After reconstitution, the volume shall be 10ml/vial.
200IU/vial. After reconstitution, the volume shall be 10ml/vial.
250IU/vial. After reconstitution, the volume shall be 10ml/vial.
300IU/vial. After reconstitution, the volume shall be 10ml/vial.
400IU/vial. After reconstitution, the volume shall be 10ml/vial.
500IU/vial. After reconstitution, the volume shall be 10ml/vial.
1000IU/vial. After reconstitution,the volume shall be 10ml/vial.
Dosage and administration
Administration: HEMORAAS® should be administered intravenously only, and the course of administration should be strictly monitored by the physician. If the product is just brought out from the refrigerator or at the low temperature in winters, it must be warmed up to 25 - 37 ℃ for dissolution. Otherwise, precipitation will likely appear. Sterile Water for Injection should be infused into the vial at the label-indicated volume. Then the vial should be swirled gently to dissolve the product and avoid any foam. After that, a transfusion syringe with filter is used for intravenous injection. The infusion usually is conducted at a rate of 60 drops per minute. After dissolution, the product should be used out within one hour without any delay. Do not refrigerate the reconstituted solution. Discard all administration equipment after use.
Dosage: The dosage must be determined according to the need of individual patient based on such factors as the body weight, presence of inhibitors, and severity of hemorrhage. The following formula provides a guide for dosage calculation:
Human Coagulation Factor Ⅷ Unites Required (IU) = 0.5 body weight (kg) desired Factor VIII Increase (% of normal)
Example: Factor VIII Unites Required (IU) = 0.5 × 50 (kg) × 30 (%) = 750 IU
The following general dosages are recommended:
1.Mild to moderate hemorrhages: Usually be treated with a single dosage of human coagulation factor Ⅷ 10-15 IU per kg to raise the factor Ⅷ to 20-30% of normal level.
2.Severe hemorrhage or in minor surgery: the plasma factor Ⅷ level of patients should be raised to 30-50% of normal level. The initial dosage is 15-25 IU per kg. The maintaining dosage 10-15 IU per kg is given at 8-12 hour intervals if required.
3.Massive hemorrhage: The life-threatening bleeding such as the mouth bleeding,urinary tract bleeding and central nervous system bleeding or hemorrhage near vital areas, such as neck, throat, retroperitoneal space and iliopsoas sheath; Should be treated with 40 IU per kg initially and repeated every 8-12 hours of the maintaining dosage 20-25 IU per kg. Physicians should determine the extent of the therapy course.
4.Surgery: Elective surgery should only be considered if the inhibitor level is within normal limits. Factor Ⅷ level should be achieved within the normal range (60-120%) at the beginning of surgery. Usually 30-40 units per kg is given prior to surgery. After surgery, level of Factor Ⅷ should be maintained at 60% of normal for 4 day and reduce to 40% for the next 4 days.
5.Development of acquired Factor Ⅷ inhibitors: Large doses of Factor Ⅷ (Human) are required. The dosage is usually more than twice of the requirement for the treatment of hemophilia A patients.
Adverse reactions
Adverse reactions may include chills, nausea, dizziness or headache. These symptoms are usually transitory. The possibility of allergic reactions exists.
Contraindications
HEMORAAS® is contraindicated in individuals who have an anaphylactic response to it.
Precautions
1.When large doses are repeatedly administered, the possibilities of allergic reaction, hemolysis and pulmonary edema should be noted, especially for the patients with cardiac diseases.
2.The product, after reconstitution is usually a clear solution, or with slight opalescence, and a few small protein particles may occasionally exist. If large insoluble particles are present do not use the product.
3.HEMORAAS® is not indicated for hemophilia B caused by the deficiency of factor Ⅸ or hemophilia C caused by the deficiency of factor Ⅺ. A correct diagnosis must be made before administration of the product.
4.Administer only by the intravenous route.
5.Administer immediately after reconstitution within one hour. Discard any unused contents.
6.Do not use the expired product. Do not use if the preparation vial is not in vacuum condition.
Pregnancy and lactation
Animal reproduction studies have not been conducted with Factor Ⅷ (Human). It is also unknown whether Factor Ⅷ (Human) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Factor Ⅷ (Human) should be given to a pregnant woman only if clearly needed.
Pediatric use
Caution should be taken in children.
Geriatric use
No relevant trials of HEMORAAS® were performed, and no relevant reference of HEMORAAS®.

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Drug interactions
HEMORAAS® should be infused singly, and can not be administered with other drugs.
Overdose
No relevant trials of HEMORAAS® were performed, and no relevant reference of HEMORAAS®.
Pharmacology and toxicology
Pharmacology: In intrinsic coagulation pathway, in the present of Ca^{2+} and phospholipid, activated factor Ⅷ act as a cofactor of activated factor Ⅸ to convert factor Ⅹ to activated factor Ⅹ, which activates prothrombin into thrombin to initiate normal coagulation process. Each unit of Factor Ⅷ per kg of body weight infused will increase the circulatory level of Factor Ⅷ by 2.0 to 2.5%.
Toxicology: No relevant trials were performed, and there is no relevant reference.
Pharmacokinetics
The biological half-life of Factor Ⅷ is about 8-12 hours.
Storage and shipping
Store and ship at 2-8℃, protected from light.
Package
Glass bottle, one vial per package.
Shelf life
24 months.
Standard for implementation
100IU: Pharmacopeia of the People's Republic of China, 2025,Volume Ⅲ and the drug registration specifications(License Number: 2017B02070);
200IU: Pharmacopeia of the People's Republic of China, 2025,Volume Ⅲ and the drug registration specifications(License Number: 2017B02007);
250IU: Pharmacopeia of the People's Republic of China, 2025,Volume Ⅲ and the drug registration specifications(License Number: 2017B02008);
300IU: Pharmacopeia of the People's Republic of China, 2025,Volume Ⅲ and the drug registration specifications(License Number: 2017B02067);
400IU: Pharmacopeia of the People's Republic of China, 2025,Volume Ⅲ and the drug registration specifications(License Number: 2017B02069);
500IU: Pharmacopeia of the People's Republic of China, 2025,Volume Ⅲ and the drug registration specifications(License Number: 2017B02068);
1000IU: Pharmacopeia of the People's Republic of China, 2025,Volume Ⅲ and the drug registration specifications(License Number: 2017B02066).
Product license No.
100IU: 国药准字S10950029 200IU: 国药准字S10950028
250IU: 国药准字S10980062 300IU: 国药准字S10950030
400IU: 国药准字S10950037 500IU: 国药准字S10980063
1000IU: 国药准字S10980064
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
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