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狂犬病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：狂犬病人免疫球蛋白
英文名称：Human Rabies Immunoglobulin
汉语拼音：Kuangquanbing Ren Mianyiqiudanbai

【成　　份】　本品系由含高效价狂犬病抗体的健康人血浆，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，不含防腐剂和抗生素。
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】　主要用于被狂犬或其他疯动物咬伤、抓伤患者的被动免疫。所有怀疑有狂犬病暴露的病人均应联合使用狂犬病疫苗和狂犬病人免疫球蛋白。如果病人接种过狂犬病疫苗并具有足够的抗狂犬病抗体滴度，仅再次接种疫苗而不使用本品。

【规　　格】　每瓶含狂犬病抗体200IU（2ml）。

【用法用量】　用法：及时彻底清创后，于受伤部位用本品总剂量的1/2作皮下浸润注射，余下1/2进行肌内注射（头部咬伤者可注射于背部肌肉）。但WHO建议：首先应尽可能多地在伤口部位注射；其次如果没有足够量的本品则应对本品进行稀释后注射；最后，将多余HRIG注射到大腿肌肉，而不是臀部肌肉。
用量：注射剂量按20IU/kg体重计算（或遵医嘱），一次注射，如所需总剂量大于10ml，可在1～2日内分次注射。随后即可进行狂犬病疫苗注射，但两种制品的注射部位和器具要严格分开。

【不良反应】　一般无不良反应，少数人有红肿、疼痛感，无需特殊处理，可自行恢复。国外已有血管神经性水肿、皮肤潮红、肾病综合症和过敏性休克文献报道。

【禁　　忌】　对人免疫球蛋白过敏或有其他严重过敏史者。

【注意事项】　1.本品不得用作静脉注射。
2.本品肌内注射不需做过敏试验。
3.如有异物或摇不散的沉淀，瓶体出现裂纹或过期失效等情况，不得使用。
无本品对动物生殖影响的研究资料，尚不清楚使用本品是否会影响生殖能力以及妊娠妇女使用本品是否对胎儿造成影响。妊娠妇女在必需使用本品时方可使用

【儿童用药】　儿童使用本品的安全性和有效性尚未确立。必需使用时请遵医嘱。

【老年用药】　老年患者用药无特殊，必需使用时请遵医嘱。

【药 物 相 互 作 用】　1.治疗性疫苗启动后，不再推荐再次使用狂犬病人免疫球蛋白，因为会妨碍主动免疫的充分表达。
2.使用本品后，三个月内不能接种麻疹等活病毒疫苗，因为抗体干扰疫苗免疫应答。

【药物过量】　无药物过量文献资料。

【药理毒理】　药理作用：本品为高效价的狂犬病抗体，能特异地中和狂犬病病毒，起到被动免疫作用。
毒理研究：尚不明确。

【药代动力学】　无人体药代动力学资料。

【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】　YBS05192019

【批准文号】　国药准字S20033032

【药品上市许可持有人】　深圳市卫光生物制品股份有限公司

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Date of approval:28.02.2007
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Instructions for Human Rabies Immunoglobulin

Please read the instructions carefully and follow the doctor's instruction.

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 alone some known or unknown infectious agents, so one must balance risk versus benefit in clinical.

[Medicine name]
English name: Human Rabies Immunoglobulin
Chinese pinyin: Kuangquanbing Ren Mianyiqiudanbai
[Composition]
The product is prepared from healthy person plasma with rather high titer of antibody of rabies virus 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.
[Property] The product should be colorless or pale yellow clear liquid,which may be opalescent, and should not be turbid.
[Indications]
Applicable for the passive immunity of patient bit or injured by dogs or animals with rabies. Any suspected patient expose to rabies shall be subject to the rabies vaccine and human rabies immunoglobulin. If the patient has been inoculated with rabies vaccine, and has enough titer of anti-rabies antibody, he only needs to be inoculated with vaccine rather than the immunoglobulin.
[Specification] Rabies antibody: 200 IU (2ml)/bottle.
[Application and dosage]
Usage: After thoroughly cleaning the wound, use 1/2 dosage of the product for subcutaneous infiltration injection on the wound. The rest 1/2 product shall be used for intramuscular injection (for the patient with head wounded, the injection shall be adopted on the back muscle). But the WHO suggests: first, the injection shall be conducted on the wounded part; next, if there are no enough products, the products shall be diluted before the injection; last, inject the redundant HRIG into the thigh muscle rather than gluteal muscle.
Dosage: the injection dosage shall be calculated as 20IU/kg (or according to the doctor's advice). Single injection. If the total dosage is more than 10ml, several injections can be conducted with 1~2 days. Subsequently, the injection of rabies vaccine can be conducted. The injection parts and apparatus for the two products shall be strictly separated.
[Side effects]
Generally, the product seldom has side effects. A few patients may have red swelling and pain sensitivity, and can be subsided without special treatment. There are some overseas reports of angioneurotic edema, skin flush, nephrotic syndrome, and anaphylactic shock.
[Contraindications]
Patients with the history of human immunoglobulin allergy or other serious allergies are prohibited to take the medicine.
[Precautions]
1.The product shall not be used for intravenous injection.
2.No allergy test shall be conducted before the intramuscular injection.
3.If the products have foreign bodies or undispersed deposits, the ampoule has crack, or the medicine is expired, the products shall not be used.
[Usage for pregnant and lactating women]
No research information for the influence of the product on the animal reproduction. The influence of the product on the reproductive capacity and the influence on the fetus are uncertain. The pregnant women may use the product when necessary.
[Usage for children]
The safety and effectiveness of the usage for children is uncertain. Abide by the doctor's advice when using.
[Usage for elder] No special requirement for usage for the elder. Abide by the doctor's advice when using.
[Interaction between medicine]
1.After the start of therapeutic vaccine, re-use of the human rabies immunoglobulin is not recommended, because the immunoglobulin will hinder the full expression of active immunization.
2.After using the product, the inoculation of live virus vaccine (e.g. measles) is prohibited within three months, because the antibody will interfere with the response of vaccine immunity.
[Drug Overdose] There is no document and report on overdosing of the product.
[Pharmacology and Toxicology]
Pharmacological action: The product is the rabies antibody, can especially neutralize the rabies virus, and produce the function of passive immunity.
Toxicology research: Not available.
[Pharmacokinetics] No information for human pharmacokinetics.
[Storage] Protect from light. Store and transport at the temperature of 2~8℃.
[Package] Packing material and container: Vail; Packing Specification: 1 bottle/case.
[Period of validity] 36 months
[Executive Standard] YBS05192019
[Approval document N.] GYZZ S20033032
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