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BIOHUI®
博晖生物

Instructions of Human Rabies Immunoglobulin

Please read the instructions carefully and use the product under the guidance of a physician

Warning: Since the source plasma comes from human blood, although the source plasma has been screened for relevant pathogens and measures to remove and inactivate viruses have been taken in the manufacturing process, theoretically, there is still a potential risk of transmitting certain known and unknown pathogens, and the pros and cons shall be weighed when used clinically.

【Drug Name】
Generic Name: Human Rabies Immunoglobulin
English Name: Human Rabies Immunoglobulin
Chinese Zhuyin: Kuangquanbing Ren Mianyiqiudanbai

【Ingredients】
Main Ingredient: Human Rabies Immunoglobulin.
Excipients: maltose, glycine.

【Appearance】
The product is a colorless or light yellow clear liquid, which may appear slightly opalescent but shall not be turbid.

【Indications】
It is mainly used for passive immunity in patients who have been bitten or scratched by rabid dogs or other animals carrying rabies virus.

【Strength】
Each vial contains 200 IU (2 ml) of rabies antibody.

【Usage and Dosage】
Usage: After prompt and thorough wound debridement, administer half of the total dose of this product via subcutaneous injection with infiltration at the site of injury, and administer the remaining half via intramuscular injection (for head injuries, inject into the dorsal muscles). According to WHO recommendations, it is advised to administer the product as much as possible at the wound site. If an adequate quantity of the product is not available, it can be diluted with normal saline at a ratio of 2 to 3 times before administration. Dosage: The injection dose is calculated at 20 IU/kg body weight (or as directed by a physician) for a single injection. If the total dose required is greater than 10ml, it can be administered in divided doses over 1-2 days. The rabies vaccine can then be injected, but the injection sites and instruments for the two products shall be kept strictly separate.

【Adverse Reactions】
The following adverse reactions/events have been monitored in human rabies immunoglobulin recipients post-marketing. Since these adverse reactions/events were spontaneously reported in a population of unknown size, their occurrence rates cannot be accurately estimated. The relevance may not be accurately determined due to the concurrent use of multiple medications.
Systemic reactions: fever, chest discomfort, malaise, chills, rigors, etc.
Reactions at the administration site: pain, erythema, swelling/redness, induration, etc.
Skin and subcutaneous tissue: rash, erythema, urticaria, erythematous eruption, papules, pruritus, hyperhidrosis, angioneurotic edema.
Nervous system: headache, dizziness, syncope, paresthesia, consciousness disorders, etc.
Gastrointestinal system: nausea, vomiting, abdominal pain, diarrhea, etc.
Immune system: anaphylactic reactions, anaphylactoid reactions, anaphylactic shock, etc.
Cardiovascular system: pallor/flushing, abnormal pulse, palpitations, hypotension, cold extremities, etc.
Respiratory system: tachypnoea, dyspnoea, etc.

Musculoskeletal system: myalgia, arthralgia, etc.
Other: vertigo, tinnitus, convulsion, hematuria, etc.

【Contraindications】

1.It is contraindicated in persons with a history of hypersensitivity to human immunoglobulin products or other severe allergies.
2.It is contraindicated in individuals with selective IgA deficiency in anti-IgA antibodies.

【Precautions】

1. The product is not intended for intravenous injection.
2.No allergy test is required for intramuscular injection of the product.
3.Do not use if the product contains foreign matters or precipitates that do not dissipate upon shaking, or if the vial is cracked, or if the product has expired or become ineffective.
4.This product is a human blood product, and despite screening and virus inactivation, the possibility of transmission of bloodborne disease due to the presence of unknown pathogens such as viruses cannot be completely excluded. When using the product, the manufacturer and batch number of the product used shall be checked and recorded.
5.The product may cause severe allergic reactions, including anaphylactic shock, which can be fatal in severe cases. Close observation is required during administration, and in case of allergic or other serious adverse reactions, the medication shall be immediately discontinued and prompt treatment initiated.
6.Patients with risk factors for thromboembolism shall be monitored for symptoms associated with thromboembolic events, such as shortness of breath, limb pain or swelling, local neurologic impairment, and chest pain.
7.Freezing is strictly prohibited during transportation and storage.

【Use in Pregnant and Lactating Women】

No specific experimental study has been conducted, and there are no systematic and reliable literature references available. It is unknown whether the use of the product will affect fertility and whether its use in pregnant women will have an effect on the fetus. Use with caution in pregnant women only when necessary and when the pros and cons have been fully weighed by a physician.

【Pediatric Use】

No specific experimental study has been conducted, and there are no systematic and reliable literature references available.

【Geriatric Use】

No specific experimental study has been conducted, and there are no systematic and reliable literature references available.

【Drug Interactions】

The product is recommended for use alone.
1.After vaccination, the use of the product is not recommended as it may interfere with the adequate expression of active immunity.
2.Live virus vaccines, such as measles, shall not be administered for three months after use of the product, as the antibodies may interfere with the immune response to the vaccine.

【Overdose】

The product may cause allergic reactions and pain at the injection site due to high dose.

【Pharmacology and Toxicology】

The product is a high-titer human rabies antibody that specifically neutralizes the rabies virus, providing passive immunity.

【Pharmacokinetics】

The biological half-life of human rabies immunoglobulin is reported to be 16 to 24 days in the relevant literature.

【Storage】

Store and transport away from light at 2-8°C.

【Packaging】

Medium borosilicate glass tube vials for injection and halogenated butyl rubber stopper for injection, 1 vial/box.

【Shelf Life】

36 months.

【Executive Standards】

YBS00052018。

【Approval No.】

GYZZ S20180005.

【Marketing Authorization Holder】

Bohui Biopharmaceutical (Hebei) Co., Ltd.

【Manufacturer】

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