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BIOHUI®
博晖生物

Package Insert for Human Tetanus Immunoglobulin

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

Warning: The product is a human blood product. 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 Tetanus Immunoglobulin
English Name: Human Tetanus Immunoglobulin
Chinese Pinyin: Poshangfeng Ren Mianyiqiudanbai

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

【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 the prevention and treatment of tetanus, especially suitable for those who have allergic reactions to tetanus antitoxin (TAT).

【Strength】
Each vial contains 250IU (2.5ml) of tetanus antibodies.

【Usage and Dosage】
Usage: The product is intended for intramuscular injection into the gluteal muscle. No skin test is required, and it must not be administered via intravenous injection.
Dosage:
1. Prophylactic Dose: 250 IU in one dose for children and adults. The dose may be doubled for individuals with severe wounds or heavily contaminated wounds.
2. Reference Therapeutic Dose: 3,000-6,000 IU. It shall be used up as soon as possible after opening and injection at multiple sites is allowed. The treatment regimen shall be as advised by the physician.

【Adverse Reactions】
Post-marketing surveillance has reported the following adverse reactions/events associated with human tetanus immunoglobulin:
Reactions at the administration site: pain, swelling, redness, induration, etc.;
Systemic reactions: fatigue, chills, fever, swelling of limbs or face, facial pallor or flushing, etc.;
Skin and subcutaneous tissue: rash, pruritus, erythema, hyperhidrosis, angioedema, etc.;
Nervous system: dizziness, headache, hypoesthesia, syncope, somnolence, etc.;
Gastrointestinal system: nausea, vomiting, diarrhea, etc.;
Immune system: hypersensitivity, anaphylactoid reaction, anaphylactic shock, etc.;
Cardiovascular system: chest discomfort, palpitations, etc.;
Respiratory system: tachypnoea, dyspnoea, laryngeal edema, etc.

【Contraindications】
Contraindicated in individuals with a history of allergy to human immunoglobulin products or any component of this product and individuals with selective IgA deficiency who have anti-IgA antibodies.

【Precautions】
1. While using this product for passive immunity, the adsorbed tetanus vaccine can be administered for active immunity, but the injection sites and equipment shall be kept separate.
2. The product shall be a clear or opalescent liquid. Trace amounts of precipitate may be present, but they shall dissolve immediately

upon shaking. 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.
3. After opening, the product shall be injected in one dose and not be used in multiple doses.
4. This product may cause allergic reactions, and anaphylactic shock may occur in severe cases. Before use, the patient's medication history and allergy history shall be carefully inquired. 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.
5. Patients with risk factors for thromboembolism shall be monitored for symptoms related to thromboembolic events, such as limb pain or swelling, chest pain, tachypnoea, local neurological dysfunction, and disturbance of consciousness.

【Use in Pregnant and Lactating Women】

No information is available on studies of the effects of the product on animal reproduction. 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. Pregnant and lactating women shall use the drug with caution. If necessary, please follow the instructions of the physician.

【Pediatric Use】

The safety and efficacy of the product in children have not been established. Use only as directed by a physician.

【Geriatric Use】

No specific experimental study has been conducted, and there are no systematic and reliable literature references available. Elderly patients shall use the product only as directed by a physician.

【Drug Interactions】

It shall be used alone.
Immunoglobulin products may interfere with responses to live virus vaccines (e.g., measles, mumps, polio, and herpes vaccines), so it is recommended that these vaccines shall be administered approximately 3 months after injection of the product. If the product is used within 3 to 4 weeks after the administration of an attenuated live vaccine, it is recommended to re-vaccinate the corresponding attenuated live vaccine 3 months after the last injection of the product.

【Overdose】

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

【Pharmacology and Toxicology】

Pharmacology: The product contains high-titer tetanus antibodies which can neutralize tetanus toxins, thereby providing preventive and therapeutic effects against clostridium tetani infection.
Toxicological Studies: unknown.

【Pharmacokinetics】

No pharmacokinetic study is available. However, it has been reported in the literature that after injection, human tetanus immunoglobulin is slowly released from the injection site into the circulatory system, reaching its maximum plasma concentration within 2 to 4 days; its half-life is approximately 3 to 4 weeks, and IgG itself or IgG complexes will be gradually cleared by the immune system.

【Storage】

Store and transport at 2 - 8 ℃ away from light.

【Packaging】

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

【Shelf Life】

36 months.

【Executive Standards】

YBS00102018

【Approval No.】

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【Marketing Authorization Holder】

Bohui Biopharmaceutical (Hebei) Co., Ltd.

【Manufacturer】

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