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Package Insert for Human Hepatitis B 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 Hepatitis B Immunoglobulin
English Name: Human Hepatitis B Immunoglobulin
Chinese Pinyin: Yixingganyan Ren Mianyiqiudanbai

[Ingredients]

Main Ingredients: Human Hepatitis B 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]

The product is mainly used for the prevention of hepatitis B, applicable to:

1. Infants born to hepatitis B surface antigen (HBsAg)-positive mothers;
2. Individuals accidentally exposed to infection;
3. Those who are in close contact with patients with hepatitis B and hepatitis B virus carriers.

[Strength]

Each vial contains 200 IU (2 ml) of anti-HBs.

[Usage and Dosage]

Usage: For intramuscular injection only, not for intravenous infusion.

Dosage:

1. Mother-infant block: Infants born to mothers with

positive HBsAg shall be injected with this product of 100IU within 24 hours after birth; refer to the instructions for hepatitis B vaccine for dosage and time of hepatitis B vaccine injection, or you can follow other appropriate protocols recommended by the doctor.

2. Hepatitis B prevention: The injection amount is 100IU for children and 200IU for adults each time. It can be injected again at an interval of 3 to 4 weeks if necessary.

3. People who are accidentally infected shall be injected with the product of 8IU-10IU/kg immediately (no later than 7 days) based on the body weight and injected again one month later.

[Adverse Reactions]

Adverse reaction monitoring data are still being accumulated and standardized. A small number of individuals may experience transient symptoms such as headache, palpitations, fever, rash, nausea, local redness and swelling, or pain, which typically resolve on their own without the need for special treatment.

[Contraindications]

1. Contraindicated in individuals with a history of allergy to immunoglobulin products or any component of this product, or those with a history of other severe allergies.
2. Contraindicated in individuals with selective IgA deficiency who have anti-IgA antibodies.

[Precautions]

1. The product is a colorless or light yellow clear liquid, which may appear slightly opalescent but shall not be turbid. Trace amounts of precipitate may be present, but they shall dissolve immediately upon shaking. Do not use if the product contains precipitates or foreign matters that do not dissipate upon shaking, or if the vial is cracked, or if the product has expired or become ineffective.
2. After opening, the product shall be injected in one dose and not be used in multiple doses or for another person.
3. Intravascular injection is strictly prohibited.

[Use in Pregnant and Lactating Women]

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

[Pediatric Use]

See [Usage and Dosage].

[Geriatric Use]

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

[Drug Interactions]

1. This product must be injected separately and not be used in combination with any other medicines.
2. Any drug that interacts with immunoglobulins may interact with the product.
3. Use of this product may interfere with the active immune response to live attenuated vaccines (such as measles, rubella, mumps, and varicella vaccines) within 3 months.

[Overdose]

The product may cause allergic reactions. Pain may occur at the injection site due to a high dose.

Pharmacological research: This product contains high-titer hepatitis B surface antibodies (anti-HBs), which can

specifically bind to the corresponding antigen to provide passive immunity.

Toxicological Studies: unknown.

[Pharmacokinetics]

No specific experimental study has been conducted. The following data are from related literature reports. After injection, the hepatitis B surface antibodies (anti-HBs) are slowly released from the injection site into the circulatory system, causing the maximum plasma concentration to be reached in 2 to 5 days. The half-life of human immunoglobulin is approximately 24 days, after which the IgG itself or the IgG-virus complex will be cleared by the human immune system.

[Storage]

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

[Packaging]

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

[Shelf Life]

24 months.

[Executive Standards]

YBS10402020 and Volume III of Chinese Pharmacopoeia (Edition 2025).

[Approval No.]

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[Marketing Authorization Holder]

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