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Instructions of Human Immunoglobulin

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

WARNING: This product is a human blood product. Despite screening and viral inactivation, the potential risk of transmitting blood-borne diseases caused by viruses or other unknown pathogens cannot be completely eliminated. The pros and cons shall be weighed in clinical use.

[Drug Name]

Generic Name: Human Immunoglobulin

English name: Human Immunoglobulin

Chinese Pinyin: Ren Mianyiqiudanbai

[Ingredients]

The main ingredient is human immunoglobulin. The product is made from healthy human plasma, with plasma proteins separated and purified by cold ethanol fractionation and chromatography, and with viruses inactivated at low pH (pH 4.0) and filtered through DV50 pH4 nanomembranes. It contains suitable glycine as a stabilizer and does not contain preservatives and antibiotics.

[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 of measles. When combined with antibiotics, it may improve the efficacy

for certain serious bacterial and viral infections.

[Strength]

300 mg/vial (10%, 3ml);

150 mg/vial (10%, 1.5ml).

[Usage and Dosage]

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

Dosage: as directed by a physician.

For prevention of measles: To prevent the onset of disease or reduce symptoms, inject 0.05~0.15 ml per kilogram of body weight within 7 days of contact with a patient with measles; children under 5 years of age shall be injected with 1.5~3.0 ml, and the maximum injection volume shall not be more than 6 ml for children over 6 years of age. The prophylactic effect of a single injection typically lasts 2 to 4 weeks.

[Adverse Reactions]

Monitoring data on adverse reactions has yet to be accumulated and normalized. A very small number of individuals may experience redness and pain at the

injection site, which does not require special treatment and can resolve on their own.

[Contraindications]

- 1.For individuals with a known allergy to immunoglobulin or a history of severe allergic reactions.
- 2.For individuals with selective IgA deficiency in anti-IgA antibodies.

[Precautions]

- 1.Do not use if the product appears turbid with visible precipitate that do not dissipate upon shaking or foreign particles, or the packaging bottle is cracked, expired or invalid.
- 2.After opening, the product shall be injected in its entirety and must not be used partially or in multiple doses.
- 3.It is strictly prohibited to freeze the product 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.

[Pediatric Use]

See [Usage and Dosage] item.

[Geriatric Use]

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

[Drug Interactions]

It shall be used alone. Any drug that interacts with immunoglobulins may interact with the product.

[Overdose]

Mutagenic reactions and pain at the injection site due to high doses may occur.

[Pharmacology and Toxicology]

Pharmacology: Immunoglobulin injection is a passive

immunotherapy. It involves administering large amounts of antibodies contained in immunoglobulins to the recipient, bringing them from a low or non-immune state to a temporary immune protective state very quickly. Because antibody-antigen interactions play a direct role in neutralizing toxins and killing bacteria and viruses, immunoglobulin products provide preventive effects against bacterial and viral infections.

Toxicological Studies: unknown.

[Pharmacokinetics]

No such targeted study is available, and the biological half-life of human immunoglobulin has been reported in the literature to be 16 to 24 days.

[Storage]

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

[Packaging]

Tube vial for antibiotic use, butyl rubber stopper, 1 vial/box.

[Shelf Life]

36 months.

[Executive Standards]

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[Approval No.]

GYZZ S20063021: 300mg/vial

GYZZ S20063020: 150mg/vial

[Marketing Authorization Holder]

Bohui Biopharmaceutical (Hebei) Co., Ltd.

[Manufacturer]

Name: Bohui Biopharmaceutical (Hebei) Co., Ltd.

Address: No. 6 Qingshan Road, Luquan Lvdao Torch Development Zone, Shijiazhuang City

Post code: 050200

Tel.: 0311-83935518