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乙型肝炎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：乙型肝炎人免疫球蛋白
英文名称：Human Hepatitis B Immunoglobulin
汉语拼音：Yixingganyan Ren Mianyiqiudanbai
- 【成份】** 本品系由含高效价乙型肝炎表面抗体的健康人血浆，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：麦芽糖、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】** 主要用于乙型肝炎预防。适用于
1. 乙型肝炎表面抗原（HBsAg）阳性母亲所生的婴儿。
2. 意外感染的人群。
3. 与乙型肝炎患者和乙型肝炎病毒携带者密切接触者。
- 【规格】** 每瓶含抗-HBs 100IU（1ml）、200IU（2ml）、400IU（4ml）。
- 【用法用量】** 用法：本品只限肌肉注射，不得用于静脉输注。
用量：
1. 母婴阻断：HBsAg阳性母亲所生婴儿出生24小时内注射本品100IU；注射乙型肝炎疫苗的剂量及时间见乙型肝炎疫苗说明书或按医生推荐的其他适宜方案。
2. 乙型肝炎预防：一次注射量儿童为100IU，成人200IU，必要时可间隔3~4周再注射一次。
3. 意外感染者，立即（最迟不超过7天）按体重注射8IU~10IU/kg，隔月再注射1次。
- 【不良反应】** 一般不会出现不良反应，少数人有红肿、疼痛感，无需特殊处理，可自行恢复。
- 【禁忌】** 1. 对免疫球蛋白过敏或有其他严重过敏史者。
2. 有IgA抗体的选择性IgA缺乏者。
- 【注意事项】** 1. 本品应为无色或淡黄色可带乳光澄明液体。久存可能出现微量沉淀，但一经摇动应立即消散，如有摇不散的沉淀或异物不得使用。
2. 瓶子破裂、过期失效者不得使用。
3. 本品开启后，应一次输注完毕，不得分次使用或给第二个人使用。
- 【孕妇及哺乳期妇女用药】** 尚不明确。
- 【儿童用药】** 尚不明确。
- 【老年用药】** 尚不明确。
- 【药物相互作用】** 尚不明确。
- 【药物过量】** 尚不明确。
- 【药理毒理】** 药理作用：本品含有高效价的乙型肝炎表面抗体，能与相应抗原专一结合起到被动免疫的作用。
毒理研究：尚不明确。
- 【药代动力学】** 尚不明确。
- 【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】** YBS05212019
- 【批准文号】** 国药准字S20013051（100IU（1ml）/瓶）、国药准字S20013052（200IU（2ml）/瓶）、
国药准字S20063109（400IU（4ml）/瓶）。
- 【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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Human Hepatitis B Immunoglobulin Instructions

Please read through the instructions and follow doctor's advice.

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.

[Drug Name]
Human Hepatitis B Immunoglobulin
Yixinggangyan Ren Misanyiqiudanbai

[Composition] Adjuvant: Amylomaltose, Chlorhydric acid, Sodium chloride.
The product is prepared from healthy person plasma with rather high titer of surface antibody of Hepatitis B and processed through the Cold Ethanol Handicraft with eliminating and deactivating the virus. It contains a proper stabilizer, and contains no antibiotics or preservative.

[Description] The product should be colorless or pale yellow clear liquid, which may be opalescent, and should not be turbid.

[Indications]
The product is mainly used for prevention of hepatitis B, suitable for:

1. The infant whose mother is with positive hepatitis B surface antigen (HBsAg);
2. Crowds suffering unexpected infection;
3. The close contactors with patients of hepatitis B or the carriers of hepatitis B virus.

[Specification] Contains anti-HBs: 100IU (1ml)/bottle, 200IU (2ml)/bottle, 400IU (4ml)/bottle.

[Administrations Usage and Dosage]
Administrations Usage: This product is confined to take intramuscular injection and must not take venoclysis.

Dosage:

1. Mother and baby blocking up: Babies born from mother presenting positive HBsAg take an injection of this product with a dose of 100IU within 24 hours after being born. As for the dosage and time about injection of hepatitis B vaccine may refer to the directions on hepatitis B vaccine or according to doctor's instructions;
2. Prevention of hepatitis B: For children, the dose of one each time injection is 100IU, while for adults it is 200IU. If necessary, it may take another injection in an interval of 3-4 weeks;
3. For unexpectedly infected, it is necessary to take immediate injection (must no later than seven days) with a dose of 8IU-10IU/kg depending on the weight, and take another injection after a month.

[Adverse Reactions]

There are no adverse reactions generally, though minority people may find flare or pain, which will recover and need no particular treatment without the need of special treatment.

[Contraindications]

1. People who are allergic to human immunoglobulin or have a record of any other severe allergy;
2. People with IgA antibody who have selective IgA deficiency.

[Precautions]

1. This product is colorless or pale yellow clear liquid that may be opalescent. There may be a minim of sediment after long-time storage, which will dissolve by shaking the bottle. The product should not be used if stubborn sediment or particulate matter stuff is found;
2. The product shall not be used if the product becomes invalid or the glass cracks.

3. Use the product one-off after opening, and more than one time of usage or applying it in another person is not allowed.

[Pregnancy and Nursing Mothers Use] Uncertain

[Pediatric Use] Uncertain

[Geriatric Use] Uncertain

[Drug Interactions] Uncertain

[Drug Overdose] Uncertain

[Pharmacology and Toxicology]

Pharmacological action: This product contains hepatitis B surface antibody of high titer, and can combine specially with corresponding antigens to play a passive immune role.

Toxicology: Uncertain

[Pharmacokinetics] Uncertain

[Storage] Stored and transported Avoiding from the light in the shade at 2-8°C.

[Package] Packing material and container: Vial; Packing Specification: 1 bottle/case.

[Validity] 36 months

[Executive Standard] YBS05212019

[Number of Documents of Approval] GYZZ No. S20013051 (100IU (1ml) /bottle) ; GYZZ No. S20013052

(200IU (2ml) /bottle) ; GYZZ No. S20063109 (400IU (4ml) /bottle) ;

[Marketing Authorization Holder] Shenzhen Weiguang Biological Products CO., LTD.

[Address] No.3402 Guangqiao Avenue, Guangming Street, Guangming New Area, ShenZhen

[Producer]

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