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## 破伤风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

### 警告

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: 破伤风人免疫球蛋白  
英文名称: Human Tetanus Immunoglobulin  
汉语拼音: Poshangfeng Ren Mianyiqiudanbai
- 【成份】** 本品系由含高效价破伤风抗体的健康人血浆,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: 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】** 主要用于预防和治疗破伤风,尤其适用于对破伤风抗毒素(TAT)有过敏反应者。
- 【规格】** 每瓶含破伤风抗体250IU(2.5ml)。
- 【用法用量】** 用法: 供臀部肌肉注射,不需作皮试,不得用作静脉注射。  
用量:  
1. 预防剂量: 儿童、成人一次用量250IU。创面严重或创面污染严重者可加倍。  
2. 参考治疗剂量: 3000~6000IU,尽快用完,可多点注射。
- 【不良反应】** 一般无不良反应。极少数人有红肿、疼痛感,无需特殊处理,可自行恢复。
- 【禁忌】** 对人免疫球蛋白类制品有过敏史者禁用。
- 【注意事项】** 1. 应用本品作被动免疫的同时,可使用吸附破伤风疫苗进行自动免疫,但注射部位和用具应分开。  
2. 制品应为澄明或可带乳光液体,可能出现微量沉淀,但一经摇动应立即消散。若有摇不散的沉淀或异物,以及玻璃有裂纹、过期失效等情况,均不得使用。  
3. 开瓶后,制品应一次注射完毕,不得分次使用。
- 【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】** 应单独使用。
- 【药物过量】** 尚不明确。
- 【药理毒理】** 药理作用: 本品含高效价的破伤风抗体,能中和破伤风毒素,从而起到预防和治疗破伤风梭菌感染的作用。  
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】** YBS05172019
- 【批准文号】** 国药准字S20053027
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## Human Tetanus Immunoglobulin Instructions

Please read the instructions carefully and follow the doctor's instruction.

### 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 some known or unknown infectious agents, so one must balance risk versus benefit in clinical.

**[Drug Name]**  
Human Tetanus Immunoglobulin  
Poshangfeng Ren Mianyiqudanhai

**[Composition]**  
The product is such a human tetanus immunoglobulin that is prepared from plasma with rather high titer of surface antibody of tetanus which is collected from the blood contributors immunized with the tetanus vaccine and processed through the cold ethanol protein fractionation and deactivating the virus. It contains a proper quantity of stabilizer, and contains no antibiotics. Merthiolate preservative may be added.  
Adjuvant: Chlorhydric acid, Sodium chloride.

**[Description]** The product is colorless or pale yellow clear liquid which may be slightly opalescent but not turbid.  
**[Indications]** The product is mainly applicable to prevent and treat tetanus, especially for the patients allergic to tetanus antitoxin.  
**[Specification]** Tetanus Immunoglobulin: 250IU (2.5ml) /bottle.

**[Administrations and Dosage]**  
Administrations: Only for intramuscular injection in hips; skin test not needed; not allowed for intravenous injection.  
Dosage:

1. Preventive dosage: 250IU or double at serious wound/wound contamination only once in children/adult;
2. Therapeutic dosage: 3000-6000IU, inject up as soon as possible, and possibly in several spots.

**[Adverse Reactions]**  
There are no adverse reactions generally, though minority patients might find flare or pain, which will recover and need no particular treatment.

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

- [Precautions]**
1. While applying the product for passive immunization, tetatoxoid may be used for active immunization, but it is necessary to keep the apparatus away from the injection spot.
  2. This product is clear or opalescent liquid. 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 is found, the product becomes invalid or there is a crack in the glass.
  3. Infuse the product one-off after being opened; more than one time usage is not allowed.

**[Pregnancy and Nursing Mothers Use]** Uncertain

**[Pediatric Use]** Uncertain

**[Geriatric Use]** Uncertain

**[Drug Interactions]** Uncertain

**[Overdose]** Uncertain

**[Pharmacology and Toxicology]**

Pharmacological action: This product contains high-potency tetanus antibody to specially neutralize tetanus toxin and thus prevent and treat the infection with clostridium tetani.

Toxicology: Uncertain

**[Pharmacokinetics]** Uncertain

**[Storage]** Avoiding from the light at 2-8°C.

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

**[Validity]** 36months

**[Executive Standard]** YBS05172019

**[Number of Documents of Approval]** GYZZ No. S20053027

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