核准日期：2007年10月30日
修改日期：2015年12月01日　2020年12月30日　2025年10月01日

CS2X01

# 人纤维蛋白原说明书

请仔细阅读说明书并在医师指导下使用

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：人纤维蛋白原
英文名： Human Fibrinogen
汉语拼音：Ren Xianweidanbaiyuan
【成分】
主要组成成分：人纤维蛋白原。本品来源于健康人血浆，经过TNBP和Tween 80混合物（S/D）处理以及100ºC 30分钟加热处理两步病毒灭活。
辅料：甘氨酸，盐酸精氨酸，枸橼酸钠
【性状】
本品为灰白色或淡黄色疏松体。复溶后应为澄明溶液，可带轻微乳光。
【适应症】
1.先天性纤维蛋白原减少或缺乏症。
2.获得性纤维蛋白原减少症：严重肝脏损伤；肝硬化；弥散性血管内凝血；产后大出血和因大手术、外伤或内出血等引起的纤维蛋白原缺乏而造成的凝血障碍。
本品新增加了100ºC 30分钟干热法病毒灭活工艺，可能会导致人纤维蛋白原体内生物活性下降和免疫原性改变，建议仅在无其他有效治疗方法又确实需要补充纤维蛋白原的情况下经权衡利弊后使用。
【规格】
0.5g/瓶。
【用法用量】
用法：使用前先将本品及灭菌注射用水预温至30～37ºC，然后按瓶签标示量(25ml)注入预温的灭菌注射用水，置30～37ºC水浴中，轻轻摇动使制品全部溶解（切忌剧烈振摇以免蛋白变性）。用带有滤网装置的输液器进行静脉滴注。滴注速度一般以每分钟60滴左右为宜。
用量：应根据病情及临床检验结果包括凝血试验指标和纤维蛋白原水平等来决定给药量。一般首次给药1–2g，如需要可遵照医嘱继续给药。
【不良反应】
尚未进行系统的临床不良反应观察，根据相关报道，少数患者会出现过敏反应和发热，严重反应者应采取应急处理措施。
本品含有不超过3%的盐酸精氨酸作为稳定剂，大剂量使用时可能存在代谢性酸中毒等风险。
【禁忌】
对本品过敏者禁用。
【注意事项】
1.本品专供静脉输注。
2.本品溶解后为澄清略带乳光的溶液，允许有少量絮状物或蛋白颗粒存在。为此用于输注的输血器应带有滤网装置。但如发现有大量或大块不溶物时，不可使用。
3.在寒冷季节溶解本品或制品刚从冷处取出温度较低的情况下，应特别注意先使制品和溶解液的温度升高到30～37ºC，然后进行溶解。温度过低往往会造成溶解困难并导致蛋白变性。
4.本品一旦溶解应尽快使用。
5. 在治疗消耗性凝血疾病时，需注意只有在肝素的保护及抗凝血酶III水平正常的前提下，凝血因子替代疗法才有效。
6. 应在有效期内使用。如配制时发现制剂瓶内已失去真空度，请勿使用。
7. 使用本品期间，应严密监测患者凝血指标和纤维蛋白原水平，并根据结果调整本品用量。
8. 由于体外活性检测方法的局限性，不同厂家生产的纤维蛋白原活性可能不完全相同，在相互替换时需要注意用量的调整。
9. 本品按标示量复溶后，含有不超过3%的盐酸精氨酸作为稳定剂，大剂量使用时可能存在代谢性酸中毒的风险，建议在使用前及使用期间进行电解质监测，根据结果调整剂量或停止使用本品。已存在代谢紊乱的患者应慎用本品。
【孕妇及哺乳期妇女用药】
对孕妇和哺乳期妇女用药应慎重，只有经过利弊权衡后认为患者确有必要使用时方可应用，并应在医生指导和严密观察下使用。
【儿童用药】
未进行此项实验且无可靠参考文献。
【老年用药】
未进行此项实验且无可靠参考文献。
【药物相互作用】
不可与其他药物同时使用。
【药物过量】
有引起血栓的危险性。
【药理毒理】
药理作用：在凝血过程中，纤维蛋白原经凝血酶酶解变成纤维蛋白，在纤维蛋白稳定因子（FXIII）作用下，形成坚实纤维蛋白，发挥有效的止血作用。
毒理研究：未进行此项实验且无可靠参考文献。
【药代动力学】
文献资料显示，未采用100ºC 30分钟干热法处理的纤维蛋白原半衰期为3–4天。本品为经过100ºC 30分钟干热法处理的纤维蛋白原，尚未进行药代动力学研究。
【贮藏】
于2–8ºC避光保存和运输。
【包装】
玻璃瓶装，每盒1瓶。
【有效期】
36个月
【执行标准】
《中华人民共和国药典》2025年版三部，药品注册标准（标准号：YBS00332007）
【批准文号】
国药准字S10950031
【上市许可持有人】
上市许可持有人名称：上海莱士血液制品股份有限公司
上市许可持有人地址：上海市奉贤区望园路2009号
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生产地址：上海市奉贤区望园路2009号
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电话：(021)–22130888　传真：(021)–37515875
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Date Approved: Oct. 30, 2007
Date Revised: Dec. 01, 2015 Dec. 30, 2020 Oct. 01, 2025

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# FIBRORAAS®-Human Fibrinogen

**Read the Package Insert Carefully and under the Instruction of Physician**

**WARNING**
This product is human-plasma-derived. Although the screening and testing measures of infectious agents and viral removal and inactivation added in the manufacture process, theoretically, there is still potential risk in the transmission of some known and even unknown infectious agents. The risk-benefit analysis should be taken before administration.

**Product name**
Generic Name: Human Fibrinogen
Active Ingredients: Human Fibrinogen. It is made from human plasma of healthy donors by separation and purification, followed by S/D treatment and heat treated at 100℃ for 30 minutes for 2 steps virus inactivation.
Excipients: Glycine, Arginine Hydrochloride, Sodium Citrate.

**Characteristics**
FIBRORAAS® is gray-white or slight yellow powder. After reconstitution, the solution is clear or slight opalescent.

**Indications**
1.Congenital hypofibrinogenaemia or fibrinogenaemia.
2.Acquired hypofibrinogenaemia: severe liver damage, cirrhosis, disseminated intravascular coagulation, disorder of blood coagulation due to fibrinogenaemia caused by obstetric hemorrhage, big surgical, trauma or internal haemorrhage.
This product has been heat treated at 100℃ for 30 minutes during manufacturing as an additional virus inactivation step. The heat treatment might cause immunogenicity changes, and reduce bioactivity in vivo. It is suggested that the physician should evaluate the benefits and risks before use, when administration of this product is indeed necessary.

**Specifications**
0.5g/vial

**Dosage and administration**
Administration: Warm FIBRORAAS® and sterile water for injection to 30-37℃ prior to reconstitution. Sterile water for injection (25ml as indicated on label) should be drawn completely into product vial. Gently rotate the vial to dissolve the lyophilized product completely. Do not vigorously shake to avoid foaming and denaturing protein. Administration by drip infusion with a filter transfusion set. The infusion rate is usually adjusted to 60 drops per minute.
Dosage: According to patient's condition and results of clinical laboratory test for hematological examination, include blood coagulation test and fibrinogen level in plasma. Generally, 1-2 grams may be given in the first treatment. To continue the subsequent treatments as prescribed by the physician.

**Adverse reactions**
Clinical data for adverse reactions are not available yet. Refer to literature, fever and anaphylactic reactions may occur in few patients. Emergency treatment should be taken in patients with severe reactions.

**Contraindications**
FIBRORAAS® is contraindicated in individuals who have an anaphylactic response to it.

**Precautions**
1.FIBRORAAS® should always be administered by intravenous injection.
2.After reconstitution, FIBRORAAS® is a clear solution with slight opalesence. A few small protein particles may occasionally exist. So a transfusion set with filter must be used in administration. The product should not be used if large insoluble particles are present.
3.If FIBRORAAS® is reconstituted in cold season or it is just taken from cold place, warm FIBRORAAS® and the diluent to 30-37℃ prior to reconstitution. Too low temperature may result in difficulties of reconstitution which may cause protein denaturation.
4.Once reconstituted, the preparation should be used immediately.
5.In the teatment of consumption coagulopathy, it should be noticed that replacement therapy of clotting factors is only effcetive if there is heparin protection and antithrombin III(AT-III) level is in the normal range.
6.Use before the expiration date. Do not use if the preparation vial is not in a vacuum condition.
7.The patient's state of thrombosis and themostasis should be controlled and adjust the dosage by results of clinical laboratory test for blood coagulation test and fibrinogen level in plasma.
8.Due to the limits of the methods of bioactivity test in vitro, the bioactivity of products may vary from different manufacturers. So the dosage should be adjusted when the products are replaced one another.
9.After reconstitution, the product contains less than 3% of Arginine Hydrochloride as excipient. The large dosage may result in hyperchloremic metabolic acidosis. It is suggested that electrolyte level should be monitored before and during administration, and based on the results to adjust the dosage or even discontinue the administration. Caution should be taken in the patients with metabolic dysfunction.

**Pregnancy and lactation**
Caution should be taken in pregnancy and lactation women. The physician must guide administration after the evaluation of benefits and risks.

**Pediatric patients**
No relevant trials of FIBRORAAS® were preformed, and no relevant reference of FIBRORAAS®.

**Geriatric patients**
No relevant trials of FIBRORAAS® were performed, and no relevant reference of FIBRORAAS®.

**Drug interactions**
FIBRORAAS® should be infused singly, and can not be administered with other drugs.

**Overdose**
There is risk of causing thrombosis when overdose.

**Pharmacology and toxicology**
During the course of blood coagulation, fibrinogen is converted into fibrin by thrombin, and forms stable fibrin in the present of activated coagulation factor XIII to have effective hemostasis functions.
Toxicology: No relevant trials were performed, and there is no relevant reference.

**Pharmacokinetics**
As the reference, the biological half-life of no heat-treated (100℃ for 30 minutes) fibrinogen is about 3-4 days. This product has been heat-treated(100℃ for 30 minutes) and no relevant pharmacokinetics studies were performed, and there is no relevant reference.

**Storage and shipping**
Store and ship at 2-8℃, protected from light.

**Package**
Glass bottle, one vial per package.

**Shelf life**
36 months

**Standard for implementation**
Volume Ⅲ of "Pharmacopeia of the People's Republic of China" (2025), Drug Standard Registration No. YBS00332007.

**Product license No.**
国药准字**S10950031**;

**Marketing Authorization Holder**
Name: Shanghai RAAS Blood Products Co., Ltd.
Address: No. 2009 Wang Yuan Road, Fengxian, Shanghai, P.R.China Zip code:201401

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Version:RAAS–FB0.5–SMS–ZG–05–2025