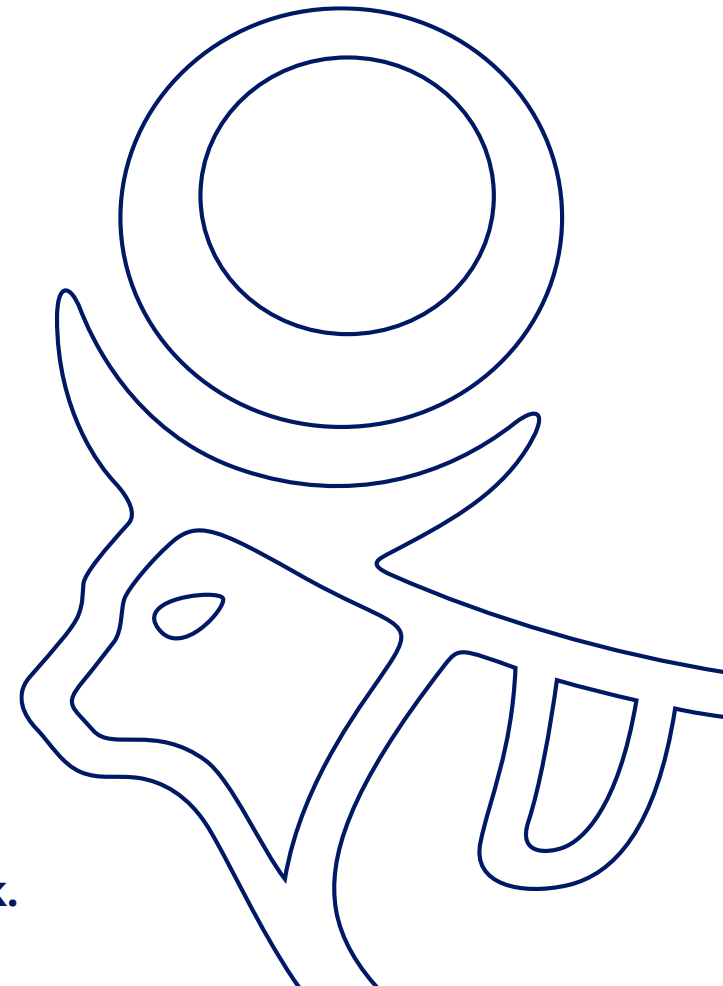


The Use of Recombinant Activated Factor VII in Patients with Glanzmann's Thrombasthenia.  
Poon MC. *Thromb Haemost.* 2021;121:332–340.  
Published online October 29, 2020.

**Disclosures for Scientific Information on Unapproved Uses**

**This information was developed and provided by Novo Nordisk.**



**Coagulation factor VIIa (recombinant) is not FDA-approved for use in patients with Glanzmann's thrombasthenia without antibodies or refractoriness to platelets, and its safety and effectiveness for this use have not been established.**

**Novo Nordisk markets NovoSeven® RT (coagulation Factor VIIa, recombinant) for the treatment of bleeding episodes and perioperative management in adults and children with hemophilia A or B with inhibitors, congenital Factor VII (FVII) deficiency, Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets, and treatment of bleeding episodes and perioperative management in adults with acquired hemophilia.**

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Please see Prescribing Information, including Boxed Warning.

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<https://www.novo-pi.com/novosevenrt.pdf>



**Novo Nordisk does not recommend the use of NovoSeven® RT in a manner that is inconsistent with the Prescribing Information.**

# Boxed Warning

## **WARNING: THROMBOSIS**

- Serious arterial and venous thrombotic events following administration of NovoSeven® RT have been reported
- Discuss the risks and explain the signs and symptoms of thrombotic and thromboembolic events to patients who will receive NovoSeven® RT
- Monitor patients for signs or symptoms of activation of the coagulation system and for thrombosis

# Contraindications; Warnings and Precautions

**Contraindications:** None known

## Warnings and Precautions

- Hypersensitivity reactions, including anaphylaxis, can occur with NovoSeven® RT. Discontinue infusion and administer appropriate treatment if symptoms appear
- Antibody to FVII may occur in FVII deficient patients. Monitor Factor VII deficient patients for prothrombin time (PT) and FVII coagulant activity, and for antibody formation to NovoSeven® RT

# Adverse Reactions and Drug Interactions

## Adverse Reactions

- The most common and serious adverse reactions in clinical trials are thrombotic events. Thrombotic adverse reactions following the administration of NovoSeven® RT in clinical trials occurred in 4% of patients with acquired hemophilia and 0.2% of bleeding episodes in patients with congenital hemophilia

## Drug Interactions

- Avoid simultaneous use of NovoSeven® RT and aPCCs (activated prothrombin complex concentrates)
- Do not administer NovoSeven® RT with coagulation factor XIII (FXIII)

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