NovoSeven® RT
Coagulation Factor VIIa (Recombinant)

Trade Unit Product Information

Brand Name	NovoSeven® RT 1 mg	NovoSeven® RT 2 mg	NovoSeven® RT 5 mg	NovoSeven® RT 8 mg
Generic Name	Coagulation Factor VIIa (Recombinant)	Coagulation Factor VIIa (Recombinant)	Coagulation Factor VIIa (Recombinant)	Coagulation Factor VIIa (Recombinant)
WAC Price	$2,570.00 per mg	$2,570.00 per mg	$2,570.00 per mg	$2,570.00 per mg
Expiration Date	36 months dating from manufactured date	30 months dating from manufactured date	30 months dating from manufactured date	30 months dating from manufactured date
Package Presentation	1 carton containing: 1 single-dose vial of NovoSeven® RT lyophilized powder, 1 pre-filled syringe of diluent for reconstitution, 1 vial adapter	1 carton containing: 1 single-dose vial of NovoSeven® RT lyophilized powder, 1 pre-filled syringe of diluent for reconstitution, 1 vial adapter	1 carton containing: 1 single-dose vial of NovoSeven® RT lyophilized powder, 1 pre-filled syringe of diluent for reconstitution, 1 vial adapter	1 carton containing: 1 single-dose vial of NovoSeven® RT lyophilized powder, 1 pre-filled syringe of diluent for reconstitution, 1 vial adapter
List number	720101	720201	720501	720801
NDC	0169 720101	0169 720201	0169 720501	0169 720801
UPC	3 0169 720101 6	3 0169 720201 3	3 0169 720501 4	3 0169 720801 5
Bar Code				
Trade Unit Dimensions (inches L × W × H)	4.125 × 2.625 × 1.75	4.125 × 2.625 × 1.75	5 × 3 × 2	5 × 3 × 2
Trade Unit Weight	0.15 lb	0.15 lb	0.2 lb	0.2 lb
Storage	Keep refrigerated or store between 36°F-77°F	Keep refrigerated or store between 36°F-77°F	Keep refrigerated or store between 36°F-77°F	Keep refrigerated or store between 36°F-77°F

Important Codes for NovoSeven® RT

Acquired hemophilia	ICD-9: 286.52[1] ICD-10: D68.311[2]
Congenital Factor VII deficiency	ICD-9: 286.3[1] ICD-10: D68.2[2]
Congenital hemophilia with inhibitors	ICD-9: 286.52[1] ICD-10: D68.311[2]
Glanzmann's thrombasthenia	ICD-9: 287.1[1] ICD-10: D69.1[2]

Indications and Usage

NovoSeven® RT (coagulation Factor VIIa, recombinant) is a coagulation factor indicated for:

- Treatment of bleeding episodes and perioperative management in adults and children with hemophilia A or B with inhibitors, congenital Factor VII (FVII) deficiency, and Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets
- Treatment of bleeding episodes and perioperative management in adults with acquired hemophilia

Important Safety Information

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

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Please see additional Important Safety Information on page 2.

Please click here for Prescribing Information, including Boxed Warning.

NovoSeven® RT Product Specification Sheet

	Administration Kit 	Travel Kit 
Product Name	**NovoSeven® RT Administration Kit** (Free of charge. Limited quantities available.)	**NovoSeven® RT Travel Case**
List Number	720006	FREE travel case available for patients who have been prescribed the product upon request from your Novo Nordisk Representative, or call 1-877-NOVO-777 (1-877-668-6777).
NDC	0169 720006	
UPC	3 0169 720006 4	
Bar Code	3 01697 20006 4	
Trade Unit Weight Dimensions (inches L × W × H)	4.125 × 2.625 × 1.5	
Trade Unit Weight	0.05 lb	
Contents	1 winged needle infusion set (25 gauge, DEHP free) 2 adhesive bandages 2 gauze pads 2 alcohol swabs 1 instructions for use	

Direct access to NovoSeven® RT is available by contacting Novo Nordisk at 1-877-NOVO-777 (1-877-668-6777) or visiting AccessNovoSevenRT.com

Important Safety Information (cont'd)

Warnings and Precautions

- Serious arterial and venous thrombotic events have been reported in clinical trials and postmarketing surveillance
- Patients with congenital hemophilia receiving concomitant treatment with aPCCs (activated prothrombin complex concentrates), older patients particularly with acquired hemophilia and receiving other hemostatic agents, and patients with a history of cardiac and vascular disease may have an increased risk of developing thrombotic events
- Hypersensitivity reactions, including anaphylaxis, can occur with NovoSeven® RT. Patients with a known hypersensitivity to mouse, hamster, or bovine proteins may be at a higher risk of hypersensitivity reactions. Discontinue infusion and administer appropriate treatment when hypersensitivity reactions occur
- Factor VII deficient patients should be monitored for prothrombin time (PT) and factor VII coagulant activity (FVII:C). If FVII:C fails to reach the expected level, or PT is not corrected, or bleeding is not controlled after treatment with the recommended doses, antibody formation may be suspected and analysis for antibodies should be performed
- Laboratory coagulation parameters (PT/INR, aPTT, FVII:C) have shown no direct correlation to achieving hemostasis

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

- Thrombosis may occur if NovoSeven® RT is administered concomitantly with Coagulation Factor XIII

References: 1. Centers for Disease Control and Prevention. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM). ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD9-CM/2011/. Accessed February 20, 2019. **2.** Centers for Disease Control and Prevention. International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM). ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2019/. Accessed February 20, 2019.

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