

# Factor VIIa & Anti-Inhibitor Complex



800.948.9834 ■ www.bdipharma.com

PRODUCT SPECIFICS	NovoSeven® RT	Feiba NF
INDICATIONS	<ul style="list-style-type: none"> <li>• Treatment of bleeding episodes in Hemophilia A or B with inhibitors and in acquired Hemophilia</li> <li>• Prevention of bleeding in surgical interventions or invasive procedures in Hemophilia A or B with inhibitors and in Acquired Hemophilia</li> <li>• Treatment of bleeding episodes in congenital FVII deficiency</li> <li>• Prevention of bleeding in surgical interventions or invasive procedures in congenital FVII deficiency</li> </ul>	For control of spontaneous bleeding episodes or to cover surgical intervention in Hemophilia A & B patients with inhibitors.
CONTRAINDICATIONS	None	<ol style="list-style-type: none"> <li>1. Patients who have known anaphylactic or severe hypersensitivity reactions to the product.</li> <li>2. Patients who are known to have normal coagulation mechanism.</li> <li>3. For the treatment of bleeding episodes resulting from coagulation factor deficiencies in the absence of inhibitors to coagulation factor VIII or coagulation factor IX.</li> <li>4. Patients with significant signs of disseminated intravascular coagulation (DIC).</li> <li>5. Patients with acute thrombosis or embolism (including myocardial infarction).</li> </ol>
VIRAL SAFETY PROCESS	Chromatographic purification process to remove exogenous viruses	Vapor Heat Treatment and 35 nm nanofiltration
PRODUCT HALF LIFE	<p><b>Hemophilia A or B</b>  <math>t_{1/2} = 2.3</math> hours (range 1.7-2.7)</p> <p><b>Congenital Factor VII deficiency</b>  <math>t_{1/2} = 2.82</math>-3.11 hours</p>	N/A; Dosing intervals: 6-12 hours by type of hemorrhage
PRODUCT RECOVERY PERCENTAGE	<p><b>Hemophilia A or B</b>                      The median in vivo plasma recovery was 44% (30-71%).</p> <p><b>Congenital Factor VII deficiency</b>                      The mean in vivo plasma recovery was approximately 20% (18.9%-22.2%).</p>	N/A
MANUFACTURING METHOD	Recombinant	Plasma
STORAGE REQUIREMENTS	Prior to reconstitution, keep refrigerated or store between 2–25°C/36–77°F. Do not freeze. Store protected from light. After reconstitution, NovoSeven® RT may be stored either at room temperature or refrigerated for up to 3 hours. Do not freeze reconstituted NovoSeven® RT or store it in syringes.	Store at room temperature, not to exceed 25 degrees C (77 degrees F). Avoid freezing, which may damage the diluent vial. Store in the original package in order to protect from light.
SHELF LIFE FROM DATE OF MANUFACTURE	36 months	24 months
DILUENT VOLUME	The specified volume of diluent corresponding to the amount of NovoSeven® RT is as follows: 1 mg (1000 micrograms) vial + 1.1 mL Histidine diluent 2 mg (2000 micrograms) vial + 2.1 mL Histidine diluent 5 mg (5000 micrograms) vial + 5.2 mL Histidine diluent 8 mg (8000 micrograms) vial + 8.1 mL Histidine diluent After reconstitution with the specified volume of diluent, each vial contains approximately 1.0 mg/mL NovoSeven® RT (1000 micrograms/mL).	500U, 1,000U: 20mL 2,500U: 50mL