

Product Specifics	NovoSeven® RT	Feiba VH
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 and patients with acquired inhibitors to FVIII, FXI and FXII
Contraindications	None	Patients who are known to have a normal coagulation mechanism
Viral Safety Process	Chromatographic purification process to remove exogenous viruses	Vapor Heat Treatment 60°C 10 hours, 190mbar., then 80°C 1 hour, 370mbar
Product Half Life	<p><b>Hemophilia A or B</b> t<sub>1/2</sub> = 2.3 hours (range 1.7-2.7)</p> <p><b>Congenital Factor VII deficiency</b> t<sub>1/2</sub> = 2.82-3.11 hours</p>	N/A; Dosing intervals: 6-12 hours
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	<p>Prior to reconstitution, keep refrigerated or store between 2°–25°C / 36°–77°F. Do not freeze. Store protected from light.</p> <p>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.</p>	Refrigeration 2°–8°C (36°–46°F). May be stored at room temperature not to exceed 25°C (77°F) for up to 6 months or until expiration date, whichever comes first
Shelf Life from Date of Manufacture	24 months	24 months
Diluent Volume	<p>The specified volume of diluent corresponding to the amount of NovoSeven® RT is as follows:</p> <p>1.0 mg (1000 micrograms) vial + 1.1 mL Histidine diluent 2.0 mg (2000 micrograms) vial + 2.1 mL Histidine diluent 5.0 mg (5000 micrograms) vial + 5.2 mL Histidine diluent</p> <p>After reconstitution with the specified volume of diluent, each vial contains approximately 1.0 mg/mL NovoSeven® RT (1000 micrograms/mL).</p>	500U, 1,000U: 20 mL 2,500U: 50 mL