NovoSeven®
Coagulation Factor VIIa (Recombinant)

For Intravenous Use Only

**INDICATIONS AND USAGE**

NovoSeven is a vitamin K-dependent glycoprotein consisting of 406 amino acids. NovoSeven is indicated for the treatment of: 1) the control of massive or uncontrolled bleeding episodes in patients who are deficient in Factor VII; 2) the prevention of bleeding in surgical interventions or invasive procedures in patients who are deficient in Factor VII; 3) the treatment of life-threatening bleeding in patients with hemophilia A or B; 4) the treatment of patients with hemophilia A or B who have inhibitors to Factor VIII or Factor IX.

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Serious adverse events were not necessarily related to dose or dose level. When the
seriousness of known adverse reactions was compared with those seen in clinical trials for
hemophilia A or B patients with inhibitors, the event rate was similar in both settings.
However, the dosing regimen and duration of therapy were different, which may
influence the frequency of adverse events.

The results of clinical trials for hemophilia A or B patients with inhibitors,
specifically the lack of thrombotic events, contrast with the results of studies for
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