

Section VI - Health Effects and First Aid

See product information for health effects of therapeutically administered doses.

Human - Occupational

Effects, including signs and symptoms of exposure:	Not tested
Medical conditions aggravated by exposure:	Not tested
Primary route(s) of entry:	Not known
Exposure guidelines:	None established

Animal Toxicity Data Single Exposure

Oral:	Not tested	IV:	Discoloration of skin at the site of injection at IV doses of 20 mg/kg.
Skin Contact:	Not tested		In mice, adverse events including convulsions and death were observed at doses of 0.88 mg/kg or greater whereas no drug-related effects were seen in doses up to 20 mg/kg in rats.
Inhalation:	Not tested		
Eye Contact:	Not tested		

Animal Toxicity Data Repeat Exposure

Target Organ Effects:	Signs of toxicity observed at doses greater than 0.33 mg/kg/day IV are considered to represent an exaggerated pharmacological action in the animal model.
Other Effects:	No general activation of the coagulation system was observed, as measured by fibrinogen, ATIII or α_2 antiplasmin.
Reproduction/Teratology:	Treatment of rats and rabbits with NovoSeven® in reproduction studies has been associated with mortality at doses up to 6 mg/kg and 5 mg/kg. At 6 mg/kg in rats, the abortion rate was 0 out of 25 litters; in rabbits at 5 mg/kg, the abortion rate was 2 out of 25 litters. Twenty three out of 25 female rats given 6 mg/kg of NovoSeven gave birth successfully, however, two of the 23 litters died during the early period of lactation. No evidence of teratogenicity was observed after dosing with NovoSeven®.
Sensitization:	Dogs showed immune complex mediated reactions similar to hypersensitivity. Rats and monkeys showed specific antibodies against rFVIIa that might have increased the rate of elimination of rFVIIa.
Mutagenicity:	Mutagenicity studies in vitro and in vivo indicated no evidence of clastogenic activity.
Carcinogenicity:	Not tested

General First Aid Recommendations

Eyes:	Flush with plenty of water. If irritation, get medical attention.
Skin:	Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation develops or persists.
Inhalation:	Move individual to fresh air. Get medical attention if breathing difficulty occurs.
Ingestion:	NovoSeven® is a protein that is readily digested by the gastric enzymes. Call a physician or poison control center if there are any untoward effects.

Section VII - Handling Precautions

Respiratory Protection:	Not required
Eye Protection:	Not required
Ventilation:	Not required
Other Protective Equipment:	Not required
Other Handling Precautions:	Not required

Section VIII - Spill, Leak and Disposal Procedures

Spills:	Wearing suitable protective clothing, absorb on appropriate material and discard. Dispose of in accordance with all local, state, and federal regulations. Wash with water.
Waste:	Avoid contamination of water sources. Dispose of any cleanup materials and waste residue according to applicable state and local regulations.

Section IX - Shipping Information

Department of Transportation:	Not regulated for surface transport.
International Civil Aviation Organization:	Not regulated for air transport.
International Maritime Organization:	Not regulated for water transport.

NovoSeven® is a registered trademark of Novo Nordisk A/S.