NovoSeven® is a recombinant factor VIIa (rFVIIa) in lyophilized form for the treatment of coagulation disorders of various aetiologies. It is indicated for the treatment of bleeding episodes in patients (including neonates) with haemophilia A or B with inhibitors. It is also used in warfarin-related bleeding, in patients undergoing surgery or invasive procedures in the presence of haemophilia A or B with inhibitors, in patients with acquired haemophilia A and in thrombotic microangiopathy (TMAs). It is also used in the treatment of shock due to thrombocytopenia. The drug is supplied as a lyophilized powder and solvent for injection.

**Pharmacological properties**

The drug contains recombinant human factor VIIa in an N-terminal domain deleted form, which differs from the wildtype rFVIIa that is used by other companies. It is indicated in the treatment of bleeding episodes in patients with haemophilia A or B with inhibitors, in patients undergoing surgery or invasive procedures in the presence of haemophilia A or B with inhibitors, in patients with acquired haemophilia A and in thrombotic microangiopathy (TMAs). It is also used in the treatment of shock due to thrombocytopenia.

**Dosage and administration**

NovoSeven® is administered by intravenous bolus injection over 2-5 minutes. The initial dose is 90 µg/kg body weight, and the dose interval should be 2-3 hours. Once treatment is no longer required, the drug may be given every 4-6 hours until haemostasis is achieved. Dose and dose interval may be adjusted in response to clinical response, and the duration of treatment should be as short as possible.

**Side effects**

The most frequent adverse drug reactions are listed by system organ class. The drug is contraindicated in patients with a history of anaphylactic reactions to any component of NovoSeven®. The most frequent adverse drug reaction is bleeding. Patients should be informed of the early signs of thrombotic events. The drug should be used with caution in patients with a history of thrombocytopenia, and the dose may need to be adjusted in these patients.

**Precautions for use**

The drug is unsuitable for use in patients with a history of thrombocytopenia, and the dose should be adjusted in these patients. The drug is not recommended for use in patients with a history of thrombosis, and the dose should be adjusted in these patients.

**Contraindications**

The drug is contraindicated in patients with a history of anaphylactic reactions to any component of NovoSeven®. The drug is contraindicated in patients with a history of thrombosis, and the dose should be adjusted in these patients.

**Pharmacokinetics**

The drug is cleared by the kidneys, and the mean volume of distribution at steady state is 196 mL/kg. The drug is rapidly cleared from plasma, and the mean elimination half-life is 2.3 hours.

**Shelf life**

The drug is supplied as a lyophilized powder and solvent for injection. The drug should be stored at 2-8°C, and the duration of stability at 2-8°C is 18 months. The drug should be protected from light exposure. The drug is stable up to 6 hours after reconstitution, and the duration of stability after reconstitution is 4-6 hours.

**Special precautions for storage**

The drug is supplied as a lyophilized powder and solvent for injection. The drug should be stored at 2-8°C, and the duration of stability at 2-8°C is 18 months. The drug should be protected from light exposure. The drug is stable up to 6 hours after reconstitution, and the duration of stability after reconstitution is 4-6 hours.

**Nature and contents of container**

The drug is supplied in a glass vial, and the drug should be protected from light exposure. The drug should be stored at 2-8°C, and the duration of stability at 2-8°C is 18 months.
NOVOSEVEN® USER INSTRUCTIONS

Preparing the solution

1. Remove the protective paper from the vial adapter without taking it out of the protective cap. Attach the vial adapter to the solvent vial. Once attached, remove the protective cap. Take care not to touch the spike on the vial adapter. If using a needle, remove needle from the packaging without taking it out of the protective cap. Screw the needle tightly onto the syringe.

2. Pull the plunger to draw in a volume of air that is equal to the amount of solvent in the solvent vial (ml equals cc on the syringe).

3. Screw the syringe tightly onto the vial adapter on the solvent vial. If using a needle, remove the protective cap and insert the needle into the rubber stopper of the solvent vial. Take care not to touch the end of the needle. Inject air into the vial by pushing the plunger until you feel a clear resistance.

Injecting the solution

4. Ensure that the plunger is pushed all the way in before you turn the syringe upside down (it may have been pushed out by the pressure in the syringe). If you use a transfer needle, make sure the needle tip is in the solvent and check that the syringe is in the solution. Hold the syringe with the solvents upside down and pull the plunger to draw all the solution into the syringe.

5. If you use a vial adapter, unscrew the vial adapter with the empty vial. If you use a transfer needle, remove the transfer needle from the solvents, replace the needle cap, and twist the needle off the syringe. NovoSeven® is now ready for injection. Follow the injection procedure as instructed by your healthcare professional.

6. Safety dispose of the syringe, vials, and unused adapters and needles as instructed by your healthcare professional.

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