•RECOMBINANT FACTOR VIIA 0.6MG/ML VIAL (2.4MG VIAL)

Class: Antihemophilic Agent

Indications:

Treatment of bleeding episodes and prevention of bleeding in surgical interventions in patients with either hemophilia A or B with inhibitors to factor VIII or factor IX, acquired hemophilia, or congenital factor VII deficiency.

Unlabeled: Warfarin-related intracerebral hemorrhage; treatment of refractory bleeding after cardiac surgery in nonhemophiliac patients

Available dosage form in the hospital:

-RECOMBINANT FACTOR VIIA 0.6MG/ML VIAL (2.4MG VIAL)

Dosage:

For I.V. administration only:

-Hemophilia A or B with inhibitors:

-Bleeding episodes: 90 mcg/kg every 2 hours until hemostasis is achieved or until the treatment is judged ineffective. Doses between 35-120 mcg/kg have been used successfully in clinical trials. The dose, interval, and duration of therapy may be adjusted based upon the severity of bleeding and the degree of hemostasis achieved. For patients experiencing severe bleeds, dosing should be continued at 3- to 6-hour intervals after hemostasis has been achieved and the duration of dosing should be minimized.

-Surgical interventions: 90 mcg/kg immediately before surgery; repeat at 2-hour intervals for the duration of surgery. Continue every 2 hours for 48 hours, then every 2-6 hours until healed for minor surgery; continue every 2 hours for 5 days, then every 4 hours until healed for major surgery.

-Congenital factor VII deficiency: Bleeding episodes and surgical interventions: 15-30 mcg/kg every 4-6 hours until hemostasis is achieved. Doses as low as 10 mcg/kg have been effective.

-Acquired hemophilia: 70-90 mcg/kg every 2-3 hours until hemostasis is achieved.

-Intracerebral hemorrhage (ICH) (warfarin-related) (unlabeled use; Freeman, 2004; Ilyas, 2008): 10-100 mcg/kg (see "**Note**" below) administered concurrently with I.V. vitamin K (to correct the nonfactor VII coagulation factors).

Note: Lower doses (10-20 mcg/kg) are generally preferred given the higher risk of thromboembolic complications with higher doses; response is highly variable; monitor INR frequently after administration since rebound increases in INR occur quickly given the short half-life of rFVIIa; duration of INR correction is dose dependent. Routine use as a sole agent is not recommended for warfarin-related ICH (Morgenstern, 2010).

-Treatment of refractory bleeding after cardiac surgery in nonhemophiliac patients: Dosing not established; doses in the range of 35-70 mcg/kg have been recommended based on low-quality evidence (case series, observational studies) (Chapman, 2011; Ferraris, 2011; Karkouti, 2007); in patients with a left ventricular assist device, lower doses (ie, 10-20 mcg/kg) may be preferred to reduce thromboembolic events (Bruckner, 2009).

Geriatric
Refer to adult dosing.

Renal Impairment :

No dosage adjustment provided in manufacturer's labeling.

Hepatic Impairment:

No dosage adjustment provided in manufacturer's labeling; use with caution.

Common side effect:

- Cardiovascular: Hypertension, bradycardia, edema, hypotension
- Central nervous system: Fever, headache, pain
- Dermatologic: Pruritus, purpura, rash
- Gastrointestinal: Vomiting
- Hematologic: Plasma fibrinogen decreased (2%), disseminated intravascular coagulation (1%), fibrinolysis increased (1%), prothrombin decreased (1%)
- Local: Injection site reaction
- Neuromuscular & skeletal: Arthrosis
- Renal: Abnormal renal function
- Respiratory: Pneumonia
- Miscellaneous: Allergic reactions

Pregnancy Risk Factor: C