The recommended dose of Bivalirudin for Injection is an intravenous (IV) bolus dose of 0.3 mg/kg, followed by an infusion of 1.75 mg/kg/h for the duration of the procedure. Five minutes after the bolus dose has been administered, an activated clotting time (ACT) should be performed and an additional bolus dose of 0.3 mg/kg should be given if needed. Extending duration of infusion post-procedure up to 4 hours should be considered if the patient has a history of thrombocytopenia or thrombosis syndrome (HPS1).

### DOSAGE FORMS AND STRENGTHS

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### INDICATIONS AND USAGE

5.2 Acute Stent Thrombosis in Patients with STEMI undergoing primary PCI. Among patients who experienced an ASI, one patient had a history of known malignancy, with an expected duration of 12 months or more. The use of Bivalirudin for Injection during brachytherapy procedures in patients receiving Bivalirudin for Injection has been observed at a greater frequency in patients with known malignancy, clinical or radiographic evidence of malignancy, or who have undergone previous radiation therapy, than in patients with no evidence of malignancy. These studies revealed no harm to the breastfed fetus attributable to bivalirudin.

### DRUG INTERACTIONS

- Bivalirudin for Injection in pregnant women. All pregnancies have a background risk of major birth defects (2.1 times the maximum recommended human dose based on body surface area). There are no adequate and well-controlled studies in pregnant women. Bivalirudin for Injection is not recommended for use in breastfed women. It is not known whether Bivalirudin for Injection is secreted in human milk. The potential for adverse reactions in the nursing infant was not evaluated. Because postmarketing adverse reactions identified during post approval use of Bivalirudin for Injection are similar to those observed in clinical trials, data from exposure in nursing mothers are not available. Unlike other heparins, Bivalirudin does not cause significant falling in antithrombin levels.

### CLINICAL STUDIES

- Comparisons of ACT results in patients undergoing percutaneous coronary intervention (PCI) including patients with heparin-induced thrombocytopenia and platelet dysfunction syndrome.

### CONTRAINDICATIONS

- Age: 65 years or older
- Sex: Female
- ASCVD: Yes
- Previous Stroke: Yes
- Previous MI: Yes
- Diabetes Mellitus: Yes
- Hypertension: Yes
- Obesity: Yes
- Smoking: Yes
- Chronic kidney disease: Yes
- Chronic obstructive pulmonary disease: Yes
- Heart failure: Yes
- Peripheral artery disease: Yes
- Liver disease: No
- Renal insufficiency: No
- Alcohol abuse: No
- Tobacco use: No
- Other comorbid conditions: Yes

### WARNINGS AND PRECAUTIONS

- Bivalirudin was administered to lactating women who were breast-feeding. Bivalirudin was administered to lactating women who were breast-feeding. Bivalirudin for Injection is contraindicated in patients with active major bleeding. The use of Bivalirudin for Injection in patients undergoing carotid artery brachytherapy may be associated with a high incidence of ischemic events compared to patient not receiving these concomitant medications.

### ADVERSE REACTIONS

- **Bivalirudin bolus injection** (2.2, 7.1) is given as a single intravenous bolus dose of 0.3 mg/kg followed by an infusion of 1.75 mg/kg/h for the duration of the procedure. Five minutes after the bolus dose has been administered, an activated clotting time (ACT) should be performed and an additional bolus dose of 0.3 mg/kg should be given if needed. Extending duration of infusion post-procedure up to 4 hours should be considered if the patient has a history of thrombocytopenia or thrombosis syndrome (HPS1).

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Reduce the infusion dose of NDC No. 20.2%

Bivalirudin for Injection is supplied as a sterile white lyophilized cake, in single-potency vials, containing 1 mg/kg of bivalirudin in sterile water for injection in approximately 2.5 mL of reconstitution fluid. Bivalirudin is metabolized by proteolytic cleavage, also

Bivalirudin does not bind to plasma proteins (other than thrombin) or to red blood cells.


dose of 15 mg/kg/day.

infusion dose of bivalirudin have been closely for signs of bleeding. There is no evidence of pure anticoagulant effect. Coagulation was assessed by activated partial thromboplastin time (APTT), PT, PT, TT, and TT, intravenous administration of bivalirudin produces an immediate anticoagulant effect. Concomitant therapy with bivalirudin increases the half-life of bivalirudin from 2.0 hours to 3.5 hours, respectively. Approximately 20% bivalirudin is cleared by hemodialysis.

The clinical relevance of these findings is unknown.

Bivalirudin is metabolized by proteolytic cleavage.

Heparin

death, MI, or revascularization therapy. The median ACT value at the time of device activation and no major bleeding was reported. Evidence for the superiority of bivalirudin to heparin was statistically significant in favor of bivalirudin in the AT -BAT Trial (NCT# 00043940).


human

approximately 25% bivalirudin is cleared to thrombin is reversible as thrombin cleaves the bivalirudin Arg-Pro Gly sequence, resulting in the release of thrombin active site tryptophan residue. Bivalirudin is a specific, direct thrombin inhibitor with a rapid onset of action (2.2).

The disposition of bivalirudin was studied in five patients with mild, moderate, and severe renal impairment. The clearance of bivalirudin was reduced approximately 70% in dialysis-dependent patients (see Clinical Pharmacology (12.3). The relationship of the infusion dose of bivalirudin in persons with renal impairment to clinical relevance is unknown.

in patients with renal dysfunction in vitro (12.3). The relationship of the infusion dose of bivalirudin in persons with renal impairment to clinical relevance is unknown.

Bivalirudin is metabolized by proteolytic cleavage.

Factor XIIIa, allowing fibrin to develop a covalently cross-linked framework which activates Factors V and VIII, promoting platelet aggregation.