

## READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

### PATIENT MEDICATION INFORMATION

#### Pr BIVALIRUDIN INJECTION

Read this carefully before you start taking BIVALIRUDIN INJECTION and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about BIVALIRUDIN INJECTION.

#### **What is BIVALIRUDIN INJECTION used for?**

**BIVALIRUDIN INJECTION** is an anticoagulant drug that is used to prevent blood from clotting. It is used in adults to treat:

- patients with ST-segment elevation myocardial infarction [STEMI (a severe type of heart attack)] undergoing Percutaneous Coronary Intervention (PCI), (a procedure that unblocks narrowed coronary arteries without having to perform surgery)
- patients with moderate- to high-risk acute coronary syndromes (ACS) due to unstable angina or non-ST segment elevation myocardial infarction (a type of heart attack) undergoing PCI, or who will be managed with medicines only, or who will have cardiac (heart) surgery called a Coronary Artery Bypass Graft (CABG) (sometimes referred to as “bypass” surgery)

BIVALIRUDIN INJECTION is intended for use with ASA (aspirin). It can also be used instead of a drug called heparin if you are at risk of having low blood cell counts due to heparin.

#### **How does BIVALIRUDIN INJECTION work?**

BIVALIRUDIN INJECTION is a direct thrombin-inhibitor that prevents blood from clotting during and after PCI or heart surgery.

#### **What are the ingredients in BIVALIRUDIN INJECTION?**

Medicinal ingredients: Bivalirudin

Non-medicinal ingredients: Glacial acetic acid, Polyethylene glycol, Sodium acetate trihydrate, Sodium hydroxide and Water for injection.

#### **BIVALIRUDIN INJECTION comes in the following dosage forms:**

A ready-to-use solution for intravenous (IV) injection. Each 50 mL vial contains 250 mg (5 mg / mL) of bivalirudin.

#### **Do not use BIVALIRUDIN INJECTION if:**

- you are allergic to bivalirudin or to any ingredient of BIVALIRUDIN INJECTION (see ‘What are the ingredients in BIVALIRUDIN INJECTION’ above)
- you have uncontrollable active bleeding
- you have a major blood clotting disorder

- you have acute stomach or intestinal ulcer
- you have bleeding in the brain
- you have severe trauma to the brain or spine
- you have a bacterial infection in your heart valves or inner layer of the heart wall (bacterial endocarditis)
- you have severe uncontrolled high blood pressure
- you have an eye problem called “retinopathy” caused by diabetes or bleeding
- you are using spinal/epidural anesthesia

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take BIVALIRUDIN INJECTION. Talk about any health conditions or problems you may have, including if you:**

- are at risk of bleeding.
- are pregnant, planning on becoming pregnant or are breastfeeding. BIVALIRUDIN INJECTION should not be used during pregnancy, unless clearly necessary. Your doctor will decide whether or not this treatment is appropriate for you.
- are taking blood thinners or medicines to prevent blood clots (anticoagulants e.g., warfarin, dabigatran, apixaban, rivaroxaban, ASA, clopidogrel, prasugrel, ticagrelor).

**Other warnings you should know about:**

**Risk of Bleeding:**

As with any drug that prevents blood from clotting, you may be at risk for bleeding during or after your PCI or heart surgery. You may be at an increased risk for bleeding if you are elderly, female or being given other drugs known to cause bleeding like heparin or warfarin. This bleeding could occur anywhere inside the body [e.g., stomach, digestive system (including vomiting blood or passing blood with the stools), abdomen, lungs, groin, bladder, heart, eye, ear, nose, or brain]. This may rarely result in a stroke or be fatal.

Signs of bleeding include:

- Nose or gum bleeds
- Blood in urine or stool
- Bruising easily
- A rash of red, round spots under the skin
- Swelling or pain in the groin or the arm
- Back pain
- Headache
- Coughing blood
- Sweating
- Feeling faint or sick or dizzy due to low blood pressure.

Talk to your doctor immediately if you are concerned about your risk for bleeding or have any of these signs of bleeding after your PCI or heart surgery.

**Blood Transfusions:**

In patients undergoing heart surgery, it is often necessary to receive a blood transfusion. In patients undergoing PCI, the need for transfusions is less common.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with BIVALIRUDIN INJECTION:**

- Drugs that break up blood clots such as heparin or warfarin
- Drugs that prevent platelets from binding together such as glycoprotein IIb/IIIa (GPIIb/IIIa) inhibitors such as Aggrastat® and Integrilin®

Using these drugs at the same time as BIVALIRUDIN INJECTION could lead to an increase in bleeding.

**How to take BIVALIRUDIN INJECTION:**

BIVALIRUDIN INJECTION is only administered by trained medical professionals through an intravenous line.

**Usual dose:**

The dose of BIVALIRUDIN INJECTION you will receive will be based on your weight and will depend on if you are having PCI or heart surgery. Your dose may be reduced if you have severe kidney problems.

**Overdose:**

If you think you have been given too much BIVALIRUDIN INJECTION, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

**What are possible side effects from using BIVALIRUDIN INJECTION?**

These are not all the possible side effects you may feel when taking BIVALIRUDIN INJECTION. If you experience any side effects not listed here, contact your healthcare professional.

- Anxiety
- Constipation
- Indigestion
- Nausea
- Nervousness
- Trouble sleeping
- Vomiting

| <b>Serious side effects and what to do about them</b>   |                                      |              |   |
|---|--------------------------------------|--------------|---|
| Symptom / effect  | Talk to your healthcare professional |              | Stop taking drug and get immediate medical help |
|   | Only if severe                       | In all cases |   |
| <b>COMMON</b>   |                                      |              |   |
| <b>Anemia</b> (decreased number of red blood cells): fatigue, loss of energy, irregular heartbeats, pale complexion, shortness of breath, weakness  |                                      | ✓            |   |
| <b>Hypotension</b> (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up)  |                                      | ✓            |   |
| Difficulty urinating or decreased urine volume  |                                      | ✓            |   |
| Fever (with or without cough and/or difficulty breathing)   |                                      | ✓            |   |
| Headache  |                                      | ✓            |   |
| Heart attack  |                                      | ✓            |   |
| <b>Arrhythmia</b> (abnormal heart rhythms): rapid, slow or irregular heartbeat  |                                      | ✓            |   |
| <b>Hypertension</b> (high blood pressure): shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse or heart palpitations |                                      | ✓            |   |
| Pain (including back, pelvic/abdominal, or chest pain)  |                                      | ✓            |   |
| Swelling of the hands and/or feet   |                                      | ✓            |   |
| <b>Hemorrhage</b> (major bleeding): at any site including at the puncture site, from the nose, in the stomach, in the respiratory tract   |                                      | ✓            |   |
| <b>Atelectasis</b> (collapsed lung): difficulty breathing, rapid, shallow breathing, wheezing, cough  |                                      | ✓            |   |
| <b>Angina</b> : chest pain or discomfort  |                                      | ✓            |   |
| <b>Pleural Effusion</b> (fluid build up in the chest cavity): shortness of breath, chest pain especially when breathing in deeply, fever, cough   |                                      | ✓            |   |
| Wound secretion   |                                      | ✓            |   |

| <b>RARE</b>   |  |   |  |
|---|--|---|--|
| <b>Allergic Reaction:</b> difficulty swallowing or breathing, wheezing; drop in blood pressure; feeling sick to your stomach and throwing up; hives or rash; swelling of the face, lips, tongue or throat.  |  | ✓ |  |
| <b>Stroke</b> (bleeding or blood clot in the brain): sudden numbness, weakness or tingling of the face, arm, or leg, particularly on one side of the body, sudden headache, blurry vision, difficulty swallowing or speaking, or lethargy, dizziness, fainting, vomiting, trouble understanding, trouble with walking and loss of balance |  | ✓ |  |

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

As BIVALIRUDIN INJECTION is a hospital product only, storage of BIVALIRUDIN INJECTION is the responsibility of healthcare professionals.

BIVALIRUDIN INJECTION will be stored in the refrigerator (2–8°C) and not frozen.

### **If you want more information about BIVALIRUDIN INJECTION:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website [www.avirpharma.com](http://www.avirpharma.com), or by calling 1-800-363-7988.

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