

# Bivalirudin ARX Powder for Injection

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using this medicine?

This medicine contains the active ingredient bivalirudin. This medicine is a medicine that stops blood clotting. It helps prevent unwanted blood clotting during an “angioplasty”.

For more information, see Section [1. Why am I using this medicine?](#) in the full CMI.

### 2. What should I know before I use this medicine?

Do not use if you have ever had an allergic reaction to bivalirudin or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use this medicine?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with this medicine and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use this medicine?

- Your doctor will give you this medicine into a vein as an injection and/or as a continuous infusion.

More instructions can be found in Section [4. How do I use this medicine?](#) in the full CMI.

### 5. What should I know while using this medicine?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are using this medicine.</li><li>If you are taking warfarin, your doctor may do some blood clotting tests after your treatment with this medicine.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not give this medicine to anyone else, even if they appear to have the same condition as you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>This medicine will be stored in the pharmacy or on the ward.</li><li>This medicine will be stored below 25°C.</li><li>After this medicine’s powder has been dissolved, the doctor will use the solution as soon as possible.</li><li>DO NOT FREEZE. Do not place in a freezer or freezing compartment of a refrigerator.</li></ul>

For more information, see Section [5. What should I know while using this medicine?](#) in the full CMI.

### 6. Are there any side effects?

This medicine (like other anticoagulants) may have unwanted or excessive bleeding as a side effect.

If any of the following happen, tell your medical or nursing staff immediately. (If you have been discharged from hospital, go to accident and emergency at your nearest hospital)

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- tightness of the chest, wheezing
- itchiness or hives

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Bivalirudin ARX Powder for Injection

**Active ingredient(s):** *Bivalirudin* (phonetic pronunciation – Bye-val-eh-roo-din)

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Bivalirudin ARX Powder for Injection. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using this medicine.**

**Where to find information in this leaflet:**

- [1. Why am I using this medicine?](#)
- [2. What should I know before I use this medicine?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use this medicine?](#)
- [5. What should I know while using this medicine?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using this medicine?

**Bivalirudin ARX contains the active ingredient bivalirudin.**

This medicine is a medicine that stops blood clotting (an anticoagulant). It helps prevent unwanted blood clotting during an “angioplasty”.

“Angioplasty” is the name of the medical procedure in which blocked blood vessels in the heart are unblocked. Angioplasty is also called “percutaneous coronary intervention (PCI)”. Angioplasty improves blood flow in the heart, helping heart problems such as angina. Your doctor unblocks the blood vessels in the heart using a fine tube (catheter) inserted through a blood vessel in the skin.

You need an anticoagulant during an angioplasty/PCI to stop unwanted blood clotting.

This medicine may also be given to you in hospital before and after angioplasty/PCI.

### How this medicine works

A protein, called “thrombin”, starts blood clotting.

Bivalirudin is an anticoagulant. It prevents blood clotting by stopping thrombin from working. This effect gradually wears off after about two hours in most people.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

There is no information from clinical studies on the safety and effectiveness of this medicine in children.

This medicine is a “Prescription Only Medicine”. Use only for the person for whom it has been prescribed.

**This medicine is for use as an anticoagulant:**

- in the treatment of patients with moderate to high risk acute coronary syndromes (ACS) (unstable angina/non-ST segment elevation myocardial**

**infarction (UA/NSTEMI) who are undergoing early invasive management, and**

- in patients undergoing percutaneous coronary intervention (PCI).**

**This medicine intended for use with aspirin.**

**A P2Y12 antagonist (eg clopidogrel or ticlopidine) may be used in addition to aspirin.**

## 2. What should I know before I use this medicine?

### Warnings

**Do not use this medicine if:**

- have, or have recently had, any bleeding from your stomach, intestines, bladder or other organs, for example, if you have noticed abnormal blood in your stools or urine (except from menstrual bleeding) because of haemostasis disorders or irreversible coagulation disorders
- have severe uncontrolled high blood pressure
- have inflammation of the heart tissue (subacute bacterial endocarditis)
- have severe kidney problems (such as kidney failure) or are on dialysis
- you are allergic to bivalirudin, or any of the ingredients listed at the end of this leaflet (such as mannitol and sodium hydroxide).
- Always check the ingredients to make sure you can use this medicine.

Symptoms of an allergic reaction may include:

- shortness of breath, tightness of the chest, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- skin rash, itching or hives

Before you are given this medicine, it is important for your doctor to know if you have medical problems other than the one this medicine is being used for.

**Check with your doctor if you:**

- tend to bleed or bruise easily
- have kidney or liver disease
- have or have had uncontrolled high blood pressure
- have any other heart condition
- take any medicines for any other condition

Your risk of bleeding may increase:

- if you are already taking medicines, especially blood-thinners/anticoagulants or medicines to prevent blood clots (anticoagulants or antithrombotics e.g. warfarin,

dabigatran, apixaban, rivaroxaban, aspirin (acetylsalicylic acid), clopidogrel, prasugrel, ticagrelor).

- if you have recently given birth or if you are pregnant

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

The active ingredient in this medicine could be excreted into breast milk. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given this medicine.

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

It may be necessary to change the dose or stop using one of the medicines. This applies to both prescription and non-prescription medicines, especially:

- other medicines used to stop blood clotting (anticoagulants), such as warfarin, or heparin (examples are Coumadin®, Clexane®, Fragmin® or Heparin Injection BP)
- medicines which affect platelets. (Platelets are blood particles involved in clotting.) Examples are aspirin (e.g. Disprin®), ticlopidine or clopidogrel (e.g. Plavix®)
- self-administered non-prescription medicines, such as St John's Wort, ginseng and ginkgo biloba

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect this medicine.**

### **4. How do I use this medicine?**

#### **How will this medicine be given**

Your doctor will give you bivalirudin into a vein as an injection and/or as a continuous infusion.

During percutaneous coronary intervention (PCI, angioplasty), bivalirudin should be given with aspirin.

Your doctor will decide how much of this medicine to give you.

If you have a kidney disease the doctor may change the usual dose.

### **If you use too much of this medicine**

As bivalirudin is given to you in a hospital under the supervision of your doctor or medical staff, it is very unlikely that you will receive an overdose.

You will be closely monitored while in the hospital so that any unwanted side effects can be treated, and you may need to stay overnight if you have certain medical conditions.

However, tell your doctor immediately if you experience side effects.

### **5. What should I know while using this medicine?**

#### **Things you should do**

**If you are taking warfarin, your doctor may do some blood clotting tests after your treatment with this medicine.**

Remind any doctor, dentist or pharmacist you visit that you are using this medicine.

Keep all your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

#### **Things you should not do**

- Do not give this medicine to anyone else, even if they appear to have the same condition as you.

#### **Looking after your medicine**

- This medicine will be stored in the pharmacy or on the ward.
- This medicine will be stored below 25°C.

**After bivalirudin powder has been dissolved, the doctor will use the solution as soon as possible.**

NOTE: the dissolved bivalirudin solution can be stored for up to 24 hours at between 2° and 8°C (the temperature of most standard refrigerators).

DO NOT FREEZE. Do not place in a freezer or freezing compartment of a refrigerator.

Bivalirudin is used for one dose in one patient only. Any remaining contents should be discarded.

Note the expiry date on the pack. Do not use after this expiry date.

Do not receive this medicine if the packaging is torn or shows signs of tampering.

**Keep it where young children cannot reach it.**

#### **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

This medicine (like other anticoagulants) may have unwanted or excessive bleeding as a side effect.

### Less serious side effects

Less serious side effects	What to do
<p><b>General:</b></p> <ul style="list-style-type: none"> <li>fever</li> </ul> <p><b>Bleeding related:</b></p> <ul style="list-style-type: none"> <li>bleeding, for example at needle puncture wounds, into the urine, or bruising where the intra-arterial catheter was inserted</li> <li>clotting of blood at the catheter site</li> <li>swelling in the blood vessels in the groin at the catheter site</li> </ul> <p><b>Vascular related:</b></p> <ul style="list-style-type: none"> <li>low blood pressure</li> <li>high blood pressure</li> <li>anaemia, decreased platelets, blood vessel disorders</li> <li>chest pain which may spread to your neck and shoulder</li> <li>heart rate changes (heart beat too slow, or too fast or irregular) which should be evaluated by a specialist</li> <li>changes in your INR levels (warfarin blood test)</li> </ul> <p><b>Pain:</b></p> <ul style="list-style-type: none"> <li>pain including at injection site, abdomen, chest or back</li> <li>aching, burning or cramping pain</li> </ul> <p><b>Gastrointestinal related:</b></p> <ul style="list-style-type: none"> <li>nausea</li> <li>vomiting</li> </ul> <p><b>Nervous system related:</b></p> <ul style="list-style-type: none"> <li>headache</li> <li>trouble falling asleep and staying asleep</li> <li>anxiety and restlessness</li> </ul> <p><b>Skin related:</b></p> <ul style="list-style-type: none"> <li>skin rash</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<p><b>Serious allergic reaction:</b></p> <ul style="list-style-type: none"> <li>swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, or other parts of the body</li> <li>tightness of the chest, wheezing</li> <li>itchiness or hives</li> <li>allergic reaction and shock (anaphylaxis)</li> <li>non-specified hypersensitivity</li> </ul> <p><b>Bleeding related:</b></p> <ul style="list-style-type: none"> <li>bleeding inside other parts of the body or the head, such as at needle puncture wounds, in the urine, or bruising where the intravenous catheter was inserted</li> <li>Thrombosis (blood clot) which may result in serious or fatal complications such as heart attack.</li> </ul> <p><b>Pain related:</b></p> <ul style="list-style-type: none"> <li>chest pain which may spread to your neck and shoulder</li> </ul> <p><b>Respiratory related:</b></p> <ul style="list-style-type: none"> <li>shortness of breath, difficulty breathing</li> <li>chest discomfort that is relieved by sitting or leaning forward</li> <li>Chest discomfort associated with shortness of breath, changing with body movements and body position</li> </ul> <p><b>Nervous system related:</b></p> <ul style="list-style-type: none"> <li>fainting, dizziness and loss of consciousness</li> </ul>	<p><b>If any of the following happen, tell your doctor and nurse immediately. (If you have been discharged from hospital, go to accident and emergency at your nearest hospital)</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What this medicine contains

<b>Active ingredient (main ingredient)</b>	250 mg of bivalirudin
<b>Other ingredients (inactive ingredients)</b>	Mannitol Sodium hydroxide
<b>Potential allergens</b>	Nil

**Do not take this medicine if you are allergic to any of these ingredients.**

This medicine does not contain gluten, lactose, sucrose, tartrazine, or any other azo dyes.

### What this medicine looks like

Bivalirudin ARX Powder for Injection is white to off-white lyophilisate powder for reconstitution for IV injection. Supplied in a clear glass vial. (AUST R 241714).

### Who distributes this medicine

Arrotex Pharmaceuticals Pty. Ltd.

15 – 17 Chapel Street

Cremorne VIC 3121

Web: [www.arrotex.com.au](http://www.arrotex.com.au)

This leaflet was prepared in May 2023.