

## Consumer Medicine Information (CMI) summary

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

### 1. Why am I taking RIVAXIB?

RIVAXIB contains the active ingredient rivaroxaban. RIVAXIB reduces the tendency of blood to form clots and is used to treat a number of conditions.

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

### 2. What should I know before I take RIVAXIB?

Do not take if you have ever had an allergic reaction to rivaroxaban 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 take RIVAXIB?](#) in the full CMI.

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

Some medicines may interfere with RIVAXIB 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 take RIVAXIB?

- Follow all directions given to you by your doctor and other health professionals carefully including:
  - How many tablets to take each day
  - If you need to take these tablets with food

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

### 5. What should I know while taking RIVAXIB?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking RIVAXIB.</li><li>• Take RIVAXIB exactly as your doctor has prescribed.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not take RIVAXIB to treat any other complaints, unless your doctor tells you to.</li><li>• Do not give RIVAXIB to anyone else, even if they have the same condition as you.</li><li>• Do not stop taking your medicine or lower the dosage without checking with your doctor first.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how RIVAXIB affects you.</li><li>• If RIVAXIB makes you feel faint or dizzy, do not drive or use machinery</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store in a cool dry place where the temperature stays below 25 °C.</li><li>• Keep your tablets in the blister pack until it is time to take them.</li></ul>

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

### 6. Are there any side effects?

All medicines have side effects. Sometimes they are serious, most of the time they are not. In serious cases, you may need medical attention. It is important to be aware of them so that you can identify any symptoms if they occur.

**Less serious side effects** include diarrhoea, indigestion or stomach pain, constipation, fever, fast heart beat, headache or pain in arms and legs.

**Serious side effects** can include prolonged excessive bleeding, severe allergic reactions, signs of liver problems, blood in urine, exceptional weakness, unexplained swelling, breathlessness, chest pain, oozing from a surgical wound or excessive skin rash.

**This is not a complete list of side effects.**

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.

# RIVAXIB®

Active ingredient: rivaroxaban

## Consumer Medicine Information (CMI)

This leaflet provides important information about taking RIVAXIB. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking RIVAXIB.**

Where to find information in this leaflet:

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

### 1. Why am I taking RIVAXIB?

RIVAXIB contains the active ingredient rivaroxaban. It belongs to a group of medicines called anticoagulants. It works by inhibiting the blood clotting protein called Factor Xa, thus reducing the tendency of blood to form clots.

RIVAXIB is used to:

- prevent blood clots in your veins after a hip or knee replacement operation because after an operation you are at an increased risk of getting blood clots
- prevent blood clots in your brain (stroke) and/or other blood vessels in your body if you have a form of irregular heart rhythm called non-valvular atrial fibrillation
- treat blood clots in the veins of your legs (deep vein thrombosis, DVT) and clots in your lung (pulmonary embolism, PE) and to prevent blood clots from re-occurring in your legs and/or lungs.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.** Your doctor may have prescribed it for another reason.

RIVAXIB is only available with a doctor's prescription. It should only be used in adults under medical supervision.

### 2. What should I know before I take RIVAXIB?

#### Warnings

**Do not take RIVAXIB if:**

- you are allergic to rivaroxaban, or any of the ingredients listed at the end of this leaflet.  
Some of the symptoms of an allergic reaction may include:
  - shortness of breath
  - wheezing or difficulty breathing
  - swelling of the face, lips, tongue or other parts of the body

- rash, itching or hives on the skin.  
Always check the ingredients to make sure you can take this medicine.
- you are bleeding excessively or at an increased risk of bleeding.
- you have a liver disease which leads to an increased risk of bleeding.
- you have end stage kidney disease or if you are undergoing dialysis (a procedure used to remove waste products from the blood). Your doctor will know how to determine your kidney function.
- you are taking medicines for fungal infection e.g. ketoconazole, itraconazole, voriconazole or posaconazole, unless they are only applied to the skin
- you are taking anti-viral medicines for HIV/AIDS e.g. ritonavir.
- you had bleeding in the brain within the last 6 months.
- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.  
If it has expired or is damaged, return to your pharmacist for disposal.

**Check with your doctor if:**

- you have any other medical conditions
- you take any medicines for any other condition
- you have kidney disease  
Doctors will need to take special care in patients with moderate or severe kidney disease. Your doctor will do tests to determine how severe your kidney disease is.
- you have kidney disease and undergoing dialysis (a procedure used to remove waste products from the blood)
- you have prosthetic heart valves
- you have liver disease
- a doctor has told you that you have a severe form of antiphospholipid syndrome (a disease which can cause blood clots)
- you have an increased risk of bleeding such as:
  - bleeding disorders
  - very high blood pressure, not controlled by medical treatment
  - an active ulcer or a recent ulcer of your stomach or bowel
  - a problem with the blood vessels in the back of your eyes
  - recent bleeding in your brain
  - a recent operation on your brain, spinal column or eye
  - abnormalities in blood vessels of your spine or brain

- o a lung disease where your bronchi are widened (bronchiectasis), or history of bleeding in the lungs.
- you have a coronary artery disease with severe symptomatic heart failure
- you have CAD and/or PAD and had the following:
  - o a bleed in your brain (stroke) or
  - o a blood clot in your brain (ischaemic, non-lacunar stroke) in the previous month or
  - o a blockage of the small arteries in the brain (lacunar stroke).
- you have an active cancer. An active cancer means that in the last 6 months you:
  - o have been diagnosed with cancer
  - o had a relapse of cancer
  - o were being treated for cancer.
- you have an intolerance to some sugars. RIVAXIB contains lactose. Contact your doctor before taking it.

Your doctor may decide to keep you under closer observation.

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**

**Do not take RIVAXIB if you are pregnant or intend to become pregnant.**

Women should use a reliable contraceptive while taking RIVAXIB.

**Do not take RIVAXIB if you are breastfeeding or intend to breastfeed.**

It is not known whether rivaroxaban passes into human breast milk.

### **Mechanical heart valve**

**Tell your doctor if you have a mechanical heart valve.**

RIVAXIB may not be suitable for you because it has not been studied in patients with a mechanical heart valve.

### **Surgery**

- **Tell your doctor, dentist or pharmacist if you need to have an operation (including dental work) while you are taking RIVAXIB.**

It is very important to take RIVAXIB and any other medications you might be on, before and after the operation exactly at the times you have been told by your doctor.

- **During any invasive procedure or operation, if it involves a catheter or injection into your spinal column (e.g. epidural or spinal anaesthesia or pain reduction):**
  - o it is very important to take RIVAXIB before and after the injection or removal of the catheter

exactly at the times you have been told by your doctor

- o tell your doctor immediately if you get numbness or weakness of your legs or problems with your bowel or bladder after the end of anaesthesia, because urgent care is necessary.

**If you have not told your doctor about any of the above, tell them before you start taking RIVAXIB.**

### **Use in children**

RIVAXIB should not be used in a child under the age of 18 years.

## **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.

**Some medicines may interfere with RIVAXIB and affect how it works. These include:**

- other medicines to reduce blood clotting e.g. enoxaparin, clopidogrel or warfarin
- some medicines to treat depression (selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs))
- anti-inflammatory and pain-relieving medicines e.g. naproxen or medicine used for the protection of heart disease e.g. acetylsalicylic acid (aspirin).

These medicines may be affected by RIVAXIB, may increase the effect of RIVAXIB or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor may decide to keep you under closer observation. If your doctor thinks that you are at increased risk of developing stomach or bowel ulcers, your doctor may also use a preventative ulcer treatment.

**Medicines that may reduce the effect of RIVAXIB include:**

- medicines for treatment of epilepsy (phenytoin, carbamazepine)
- St John's Wort, a herbal product used for depression
- rifampicin, an antibiotic.

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

## **4. How do I take RIVAXIB?**

### **How much to take**

- To prevent clots in your veins after a hip or knee replacement operation, the dose is one RIVAXIB 10 mg tablet ONCE a day with or without food.
- To prevent blood clots in brain (stroke) and other blood vessels, the usual dose is one RIVAXIB 20 mg tablet ONCE daily.

If your kidneys are not working properly, your doctor may reduce your dose to one RIVAXIB 15 mg tablet ONCE daily.

- The tablet packs are marked with days of the week to help you remember if you have taken your daily dose. RIVAXIB 15 mg and 20 mg tablets are to be taken with food.
- To treat blood clots in your legs and clots in your lungs and for preventing blood clots from re-occurring, the usual dose is one RIVAXIB 15 mg tablet TWICE daily for the first three weeks. After the first three weeks, take one RIVAXIB 20 mg tablet ONCE daily. After 6 to 12 months treatment your doctor may decide to continue treatment with either one RIVAXIB 20 mg tablet ONCE a day or one RIVAXIB 10 mg tablet ONCE a day. RIVAXIB 15 mg and 20 mg tablets are to be taken with food.

### How to take RIVAXIB

- Swallow the tablets whole with a full glass of water.
- If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take RIVAXIB. The tablet may be crushed and mixed with water or apple puree immediately before you take it. This drink should be immediately followed by food.
- If necessary, the crushed RIVAXIB tablet may be given to you through a stomach tube.
- After giving the crushed RIVAXIB tablet via the stomach tube, you or your carer should flush the tube with water. If you are taking the 15 or 20 mg RIVAXIB tablet, you should be fed via the stomach tube straight after your dose of RIVAXIB.

### When to take RIVAXIB

- Following hip or knee replacement operation: Take the first tablet 6 to 10 hours after your operation or as advised by your doctor. Then take a tablet every day for the duration prescribed, unless your doctor tells you to stop.

If you have had a hip replacement you will usually take the tablets for 5 weeks. If you have had a knee replacement you will usually take the tablets for 2 weeks. Your doctor will advise you about the exact duration.

- For prevention of stroke or treatment or prevention of blood clots in your legs and/or lungs, take the tablet(s) every day until your doctor tells you to stop. Your doctor will decide how long you must continue your treatment.
- If your heart beat needs to be restored to normal by a procedure called cardioversion, take RIVAXIB according to your doctor's instructions.
- If you need a procedure to treat blocked blood vessels in your heart (called a percutaneous coronary intervention – PCI with an insertion of a stent), the dose may be changed by your doctor.
- Your doctor will advise you about any changes to the amount of RIVAXIB you should take.
- Try to take the tablet(s) at the same time every day to help you remember.

### How long to take RIVAXIB for

- **Continue taking your medicine for as long as your doctor tells you.**
- It is important that you follow instructions from your doctor and not to miss or stop taking your medicine or lower the dosage without checking with your doctor. RIVAXIB has been prescribed to you by your doctor to treat and/or prevent a serious medical condition.

### If you forget to take RIVAXIB

RIVAXIB should be taken regularly at the same time each day.

- **If you are taking one RIVAXIB tablet ONCE a day:**  
If you have missed a dose, take it as soon as you remember. **Do not take more than one tablet in a single day to make up for a forgotten dose.** Take the next tablet on the following day and then carry on taking a tablet ONCE a day as normal. **Do not take a double dose to make up for a forgotten tablet.** This may increase the chance of you getting an unwanted side effect.
- If you are taking one RIVAXIB 15 mg tablet TWICE a day and have missed a dose, take it as soon as you remember.  
If you are taking one RIVAXIB 15 mg tablet TWICE a day and have missed a dose, take it as soon as you remember. If you forget to take a dose; you can take two RIVAXIB 15 mg tablets at the same time to get a total dose of 30 mg in one day. The following day onwards, you should take one RIVAXIB 15 mg tablet twice a day as normal, until required.
- **If you have trouble remembering to take your medicine, ask your pharmacist for some hints.**

### If you take too much RIVAXIB

If you think that you or anyone else has taken too much RIVAXIB, urgent medical attention may be needed.

Taking too much RIVAXIB increases the risk of bleeding.

#### You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while taking RIVAXIB?

### Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking RIVAXIB.
- Take RIVAXIB exactly as your doctor has prescribed.

## Call your doctor straight away if:

- you need to have a surgical or dental procedure. Tell the doctor, dentist, surgeon or anaesthetist that you are taking RIVAXIB.
- your doctor is planning for you to have an anaesthetic injection in your back (spinal or epidural injection).
- you are prescribed other medications during the course of therapy with RIVAXIB.
- you become pregnant while you are taking RIVAXIB.

Remind any doctor, dentist or pharmacist you visit that you are taking RIVAXIB.

## Things you should not do

- Do not take RIVAXIB to treat any other complaints unless your doctor tells you to.
- Do not give RIVAXIB to anyone else, even if they have the same condition as you.
- Do not stop taking RIVAXIB or lower the dosage without checking with your doctor first because RIVAXIB treats and prevents serious conditions.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

## Driving or using machines

### Be careful before you drive or use any machines or tools until you know how RIVAXIB affects you.

This medicine may cause dizziness or light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

## Looking after your medicine

- Keep your tablets in their blister pack until it is time to take them.

If you take the tablets out of the box or blister pack, they may not keep well. Follow the instructions on how to take care of your medicine properly

- Store below 25 °C.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat or dampness can destroy some medicines.

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

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

## Getting rid of any unwanted medicine

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

Do not take 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.

### Less serious side effects

Less serious side effects	What to do
<p><b>Gastrointestinal-related:</b></p> <ul style="list-style-type: none"><li>• diarrhoea, indigestion, or stomach pain</li><li>• constipation</li><li>• feeling sick (nausea)</li></ul> <p><b>Heart-related:</b></p> <ul style="list-style-type: none"><li>• fast heart beat</li></ul> <p><b>General disorders/Other:</b></p> <ul style="list-style-type: none"><li>• tiredness, pale skin and breathlessness</li><li>• fever</li><li>• headache</li></ul> <p><b>Musculoskeletal-related:</b></p> <ul style="list-style-type: none"><li>• pain in the arms or legs</li></ul> <p><b>Immune system-related:</b></p> <ul style="list-style-type: none"><li>• frequent infections such as severe chills, sore throat and mouth ulcers</li></ul> <p><b>Skin-related:</b></p> <ul style="list-style-type: none"><li>• mild rash, itchy skin</li><li>• bruising</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>Bleeding-related:</b></p> <ul style="list-style-type: none"><li>• prolonged or excessive bleeding from gums, nose etc</li><li>• heavy menstrual bleeding</li></ul> <p>Like other similar medicines (anticoagulants), RIVAXIB may cause bleeding, which may potentially be life-threatening. In some cases, this bleeding may not be obvious. There is no antidote available to reverse the effects of RIVAXIB, however there are measures your health professional can take to control/stop the bleeding. Please see your doctor if you experience any symptoms of bleeding.</p> <p><b>Allergy-related:</b></p>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>signs such as rash, itching or hives on skin, swelling of the face, lips, tongue, or other parts of the body, shortness of breath, wheezing or trouble breathing</li> </ul> <p><b>Gastrointestinal-related:</b></p> <ul style="list-style-type: none"> <li>signs of liver problems such as yellowing of the skin and/or eyes (jaundice)</li> <li>blood in the urine or stool</li> <li>vomiting or coughing up blood</li> </ul> <p><b>Renal-related:</b></p> <ul style="list-style-type: none"> <li>blood in urine, reduced urine output, swelling of the ankles, feet and legs, increased time for blood to clot, and heavy bleeding. These symptoms may be related to a condition called anticoagulant-related nephropathy.</li> </ul> <p><b>Respiratory-related:</b></p> <ul style="list-style-type: none"> <li>breathlessness, chest pain</li> </ul> <p><b>Nervous system-related:</b></p> <ul style="list-style-type: none"> <li>dizziness, fainting</li> <li>exceptional weakness</li> </ul> <p><b>Musculoskeletal-related:</b></p> <ul style="list-style-type: none"> <li>numbness in the arms and legs</li> <li>unexplained swelling</li> </ul> <p><b>Skin-related:</b></p> <ul style="list-style-type: none"> <li>skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals</li> <li>extensive skin rash associated with fever</li> </ul> <p><b>Injury/wound-related:</b></p> <ul style="list-style-type: none"> <li>oozing from a surgical wound</li> </ul>	

Your doctor may need to monitor and conduct blood tests, as RIVAXIB can affect your liver or pancreatic enzymes.

You may not experience any specific symptoms.

Your doctor may decide to keep you under observation or change how you should be treated.

**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 RIVAXIB contains

<b>Active ingredient (main ingredient)</b>	rivaroxaban 10 mg, 15 mg or 20 mg
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>croscarmellose sodium</li> <li>hypromellose</li> <li>lactose monohydrate</li> <li>magnesium stearate</li> <li>microcrystalline cellulose</li> <li>sodium lauryl sulfate</li> <li>Insta Moistshield Aqua II A22E01115 Pink; ID 139951 (15 mg tablets only)</li> <li>Insta Moistshield Aqua II A22E01116 Pink ID 139952 (10 mg tablets only)</li> <li>Insta Moistshield Aqua II A22E01569 Reddish Brown; ID 144901 (20 mg tablets only)</li> </ul>
<b>Potential allergens</b>	lactose

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

### What RIVAXIB looks like

RIVAXIB 10 mg film coated tablets are light pink to pink coloured, film coated, round, biconvex, bevelled edge tablet, debossed with "RX" on one side and "2" on the other side (AUST R 346612).

RIVAXIB 15 mg film coated tablets are pink to brick red coloured, film coated, round, biconvex, bevelled edge tablet, debossed with "RX" on one side and "3" on the other side (AUST R 346611).

RIVAXIB 20 mg film coated tablets are a reddish brown coloured, film coated, round, biconvex, bevelled edge tablet, debossed with "RX" on one side and "4" on the other side (AUST R 346610).

### Who distributes RIVAXIB

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

This leaflet was prepared in March 2025.

RIVAXIB® is a Viatris company trade mark

RIVAXIB\_cmi\Mar25/00