

ARX-RIVAROXABAN TABLETS

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 ARX-RIVAROXABAN?

ARX-RIVAROXABAN contains the active ingredient rivaroxaban. ARX-RIVAROXABAN 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 using ARX-RIVAROXABAN?](#) in the full CMI.

2. What should I know before I use ARX-RIVAROXABAN?

Do not use if you have ever had an allergic reaction to ARX-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 use ARX-RIVAROXABAN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ARX-RIVAROXABAN 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 ARX-RIVAROXABAN?

Follow all directions given to you by your doctor and other health professionals carefully including:

- How much ARX-RIVAROXABAN to take each day
- If you need to take ARX-RIVAROXABAN with food

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

5. What should I know while using ARX-RIVAROXABAN?

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

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

6. Are there any side effects?

Call your doctor immediately or go to the nearest emergency department if you feel dizzy or faint, or if you have any form of excessive bleeding, from the nose, the gums, lips, mouth, and genitals. Vomiting or coughing blood or heavy prolonged menstrual bleeding.

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.

ARX-RIVAROXABAN TABLETS

rivaroxaban

Consumer Medicine Information (CMI)

This leaflet provides important information about using ARX-RIVAROXABAN. **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 ARX-RIVAROXABAN.**

Where to find information in this leaflet:

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

1. Why am I using ARX-RIVAROXABAN?

ARX-RIVAROXABAN contains the active ingredient rivaroxaban. ARX-RIVAROXABAN is 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.

ARX-RIVAROXABAN is used for

- Prevention of 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.
- Prevention of 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.
- Treatment of 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.

2. What should I know before I use ARX-RIVAROXABAN?

Warnings

Do not use ARX-RIVAROXABAN if:

- you are allergic to rivaroxaban, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

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

Do not take ARX-RIVAROXABAN

- if you are bleeding excessively or at an increased risk of bleeding
- if you have liver disease which leads to an increased risk of bleeding
- if 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.
- if you are taking medicines for fungal infections e.g. ketoconazole, or itraconazole, voriconazole, or posaconazole, unless they are only applied to the skin
- if you are taking anti-viral medicines for HIV/AIDS e.g. ritonavir
- if you had bleeding in the brain within the last 6 months.

Check with your doctor if you:

- have any other medical conditions
- if you have kidney disease. Your doctor 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.
- if you have kidney disease and undergoing dialysis (a procedure used to remove waste products from the blood)
- if you have prosthetic heart valves
- if you have liver disease
- if a doctor has told you that you have a severe form of antiphospholipid syndrome (a disease which can cause blood clots)
- if 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
 - a lung disease where your bronchi are widened (bronchiectasis), or history of bleeding in the lungs. Your doctor may decide to keep you under closer observation.
- take any medicines for any other condition

In the event of a surgery

Tell your doctor, dentist or pharmacist if you need to have an operation (including dental work) while you are taking ARX-RIVAROXABAN. It is very important to take ARX-RIVAROXABAN 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. for epidural or spinal anaesthesia or pain reduction):

- it is very important to take ARX-RIVAROXABAN before and after the injection or removal of the catheter exactly at the times you have been told by your doctor
- 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

ARX-RIVAROXABAN contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking it.

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 use this medicine if you are pregnant or intend to become pregnant. Women should use a reliable contraceptive while taking ARX-RIVAROXABAN.

Do not use ARX-RIVAROXABAN if you are breastfeeding. It is not known whether rivaroxaban passes into human breast milk.

Mechanical heart valve

Tell your doctor if you have a mechanical heart valve. ARX-RIVAROXABAN may not be suitable for you because it has not been studied in patients with mechanical heart valve.

Child under the age of 18 years

- This medicine 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 ARX-RIVAROXABAN 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 medicines used for the protection of heart disease e.g. acetylsalicylic acid (aspirin)
- medicines for treatment of epilepsy (phenytoin, carbamazepine) St John's Wort, a herbal product used for depression
- Rifampicin, an antibiotic

These medicines may be affected by ARX-RIVAROXABAN, may increase the effect of ARX-RIVAROXABAN or may affect how well ARX-RIVAROXABAN works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking ARX-RIVAROXABAN.

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

4. How do I use ARX-RIVAROXABAN?

How much to take

- To prevent clots in your veins after a hip or knee replacement operation, the dose is one ARX-RIVAROXABAN 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 ARX-RIVAROXABAN 20 mg tablet once daily. If your kidneys are not working properly, your doctor may reduce your dose to one ARX-RIVAROXABAN 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. ARX-RIVAROXABAN 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 reoccurring, the usual dose is one ARX-RIVAROXABAN 15 mg tablet TWICE daily for the first three weeks, followed by one ARX-RIVAROXABAN 20 mg tablet ONCE daily. The initial treatment pack (42 tablet pack) is marked with days of the week and "am" for the morning dose and "pm" for the evening dose. This will help you remember if you have taken the required dose. After 6 to 12 months treatment your doctor may decide to continue treatment with either one ARX-RIVAROXABAN 20 mg tablet ONCE a day or one ARX-RIVAROXABAN 10 mg tablet ONCE a day. ARX-RIVAROXABAN 15 mg and 20 mg tablets are to be taken with food.
- If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take ARX-RIVAROXABAN. 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 ARX-RIVAROXABAN tablet may be given to you through a stomach tube.
- After giving the crushed ARX-RIVAROXABAN tablet via the stomach tube, you or your carer should flush the tube with water.
- If you are taking the 15 or 20 mg ARX-RIVAROXABAN tablet, you should be fed via the stomach tube straight after your dose of ARX-RIVAROXABAN.
- Follow the instructions provided and use ARX-RIVAROXABAN until your doctor tells you to stop.

When to take ARX-RIVAROXABAN

ARX-RIVAROXABAN should be used 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 heartbeat needs to be restored to normal by a procedure called cardioversion, take ARX-RIVAROXABAN 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 ARX-RIVAROXABAN you should take.

If you forget to use ARX-RIVAROXABAN

ARX-RIVAROXABAN should be used regularly at the same time each day.

If you are taking one ARX-RIVAROXABAN 10 mg, or one 15 mg, or one 20 mg 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.**

If you are taking one ARX-RIVAROXABAN 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 ARX-RIVAROXABAN 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 ARX-RIVAROXABAN 15 mg tablet twice a day as normal, until required.

If you use too much ARX-RIVAROXABAN

If you think that you have used too much ARX-RIVAROXABAN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), 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 using ARX-RIVAROXABAN?

Things you should do

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

Call your doctor straight away if:

- You need to have a surgical or dental procedure.
- Your doctor is planning for you to have an anaesthetic injection in your back (spinal or epidural injection).
- Are prescribed other medications during the course of therapy with ARX-RIVAROXABAN
- You become pregnant while you are taking ARX-RIVAROXABAN

Remind any doctor, dentist or pharmacist you visit that you are using ARX-RIVAROXABAN.

Things you should not do

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ARX-RIVAROXABAN affects you.

If this medicine makes you feel faint or dizzy, do not drive or use machinery.

Looking after your medicine

- Keep your tablets in their blister pack until it is time to take them.
- Store the tablets in a cool dry place where the temperature stays below 25° C.

Follow the instructions in the carton on how to take care of your medicine properly.

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 windowsills.

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.

Less serious side effects

Less serious side effects	What to do
<p>Gastrointestinal:</p> <ul style="list-style-type: none"> diarrhoea, indigestion, or stomach pain constipation feeling sick (nausea) <p>Heart:</p> <ul style="list-style-type: none"> fast heart beat <p>General disorders/Other:</p> <ul style="list-style-type: none"> tiredness, pale skin and breathlessness fever headache <p>Musculoskeletal:</p> <ul style="list-style-type: none"> pain in the arms or legs <p>Immune system:</p> <ul style="list-style-type: none"> frequent infections such as severe chills, sore throat and mouth ulcers <p>Skin-related:</p> <ul style="list-style-type: none"> mild rash, itchy skin bruising 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Bleeding:</p> <ul style="list-style-type: none"> prolonged or excessive bleeding from gums, nose, etc heavy menstrual bleeding <p>Severe allergy:</p> <ul style="list-style-type: none"> signs such as rash, itching or hives on skin, swelling of the face, lips, 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you</p>

<p>tongue, or other parts of the body, shortness of breath, wheezing or trouble breathing</p> <p>Gastrointestinal-related:</p> <ul style="list-style-type: none"> signs of liver problems such as yellowing of the skin and/or eyes (jaundice) blood in the urine or stool vomiting or coughing up blood <p>Respiratory-related:</p> <ul style="list-style-type: none"> breathlessness, chest pain <p>Nervous system-related:</p> <ul style="list-style-type: none"> dizziness, fainting exceptional weakness <p>Musculoskeletal-related:</p> <ul style="list-style-type: none"> numbness in the arms and legs unexplained swelling <p>Skin-related:</p> <ul style="list-style-type: none"> skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals <p>Injury/wound-related:</p> <ul style="list-style-type: none"> oozing from a surgical wound <p>Anticoagulant-related nephropathy</p> <ul style="list-style-type: none"> blood in urine reduced urine output swelling of the ankles, feet and legs increased time for blood to clot heavy bleeding 	<p>notice any of these serious side effects.</p>
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Your doctor may need to monitor and conduct blood tests, as ARX-RIVAROXABAN can affect your liver or pancreatic enzymes. You may not experience any specific symptoms.

Like other similar medicines (anticoagulants), ARX-RIVAROXABAN 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 ARX-RIVAROXABAN, 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.

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. 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 ARX-RIVAROXABAN contains

Active ingredient (main ingredient)	rivaroxaban
Other ingredients (inactive ingredients)	microcrystalline cellulose, croscarmellose sodium, lactose monohydrate, hypromellose, sodium lauryl sulfate, magnesium stearate, Opadry Pink 03F540112 (10 mg ARTG: 140394), Opadry Brown 03F565079 (15 mg ARTG: 140395), Opadry II Brown 85F565098 IH (20 mg ARTG: 140396)

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

What ARX-RIVAROXABAN looks like

ARX-RIVAROXABAN 10 mg – Round, light red, biconvex film-coated tablets having “A1” debossed on one side and plain on other side (Aust R 357805).

It is packed in blister packs in cartons of 3, 10, 14, 15, 28, 30 and 100 tablets.

ARX-RIVAROXABAN 15 mg – Round, red, biconvex film-coated tablets having “A2” debossed on one side and plain on other side (Aust R 357809).

It is packed in blister packs in cartons of 7, 14, 28, 30, 42, 84, 98 and 100 tablets.

ARX-RIVAROXABAN 20 mg – Dark red coloured, oval shaped, biconvex film coated tablet with “A3” debossed on one side and plain on other side (Aust R 357803).

It is packed in blister packs in cartons of 7, 14, 28, 30, 84, 98 and 100 tablets.

Not all pack sizes may be marketed.

Who distributes ARX-RIVAROXABAN

Arrotex Pharmaceuticals Pty Ltd

15 -17 Chapel Street

Cremorne VIC 3121

www.arrotex.com.au

This leaflet was prepared in October 2023.