

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 XARELTO?

XARELTO contains the active ingredient rivaroxaban. XARELTO 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 XARELTO?](#) in the full CMI.

2. What should I know before I use XARELTO?

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

3. What if I am taking other medicines?

Some medicines may interfere with XARELTO 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 XARELTO?

- 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 use XARELTO?](#) in the full CMI.

5. What should I know while using XARELTO?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking XARELTO.• Take XARELTO exactly as your doctor has prescribed.•
Things you should not do	<ul style="list-style-type: none">• Do not take XARELTO 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.
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 XARELTO 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">• Store in a cool dry place where the temperature stays below 30°C.• Keep your tablets in their blister pack until it is time to take them.

For more information, see Section [5. What should I know while using XARELTO?](#) 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.

Serious side effects can include bleeding, severe allergic reactions, gastrointestinal-related, renal-related, respiratory-related, nervous system-related, musculoskeletal-related, skin-related and/or injury/wound-related reactions.

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.

XARELTO®

Active ingredient(s): *rivaroxaban*

Consumer Medicine Information (CMI)

This leaflet provides important information about using XARELTO. **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 XARELTO.**

Where to find information in this leaflet:

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

1. Why am I using XARELTO?

XARELTO contains the active ingredient rivaroxaban. XARELTO is an anticoagulant. It works by inhibiting the blood clotting protein called Factor Xa, thus reducing the tendency of blood to form clots.

XARELTO 10, 15 and 20 mg tablets are 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.

XARELTO 2.5 mg tablets twice daily along with aspirin 100 mg once daily, is used to:

- prevent major heart related events (stroke, heart attack and death from heart related conditions) if you have poor blood flow in the blood vessels of your heart (coronary artery disease or CAD) and/or arms and legs (peripheral artery disease or PAD).

2. What should I know before I use XARELTO?

Warnings

Do not use XARELTO 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.

- you are bleeding excessively or at an increased risk of bleeding
- you have 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 infections e.g. ketoconazole, or 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

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
 - 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:
 - a bleed in your brain (stroke) or
 - a blood clot in your brain (ischaemic, non-lacunar stroke) in the previous month or

- a blockage of the small arteries in the brain (lacunar stroke)
- you have an active cancer – this may also mean you have an increased risk of bleeding.
An active cancer means that in the last 6 months you:
 - have been diagnosed with cancer
 - had a relapse of cancer
 - were being treated for cancer
- You have an intolerance to some sugars. XARELTO contains lactose. 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 XARELTO.

Do not use XARELTO 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. XARELTO 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 XARELTO.**
It is very important to take XARELTO 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 XARELTO 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
- If you have not told your doctor about any of the above, tell them before you start taking XARELTO.

Use in children

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 XARELTO and affect how it works.

- 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).

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.

If you have CAD and/or PAD, your doctor may ask you to take your XARELTO 2.5 mg tablet twice daily with aspirin 100 mg once daily.

Medicines that may reduce the effect of XARELTO 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 XARELTO.

4. How do I use XARELTO?

How much to take / use

- To prevent clots in your veins after a hip or knee replacement operation, the dose is one XARELTO 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 XARELTO 20 mg tablet once daily.
If your kidneys are not working properly, your doctor may reduce your dose to one XARELTO 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. XARELTO 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 XARELTO 15 mg tablet TWICE daily for the first three weeks.
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 the first three weeks, take one XARELTO 20 mg tablet ONCE daily. After 6 to 12 months treatment your doctor may decide to continue treatment with either one XARELTO 20 mg tablet ONCE a day or one XARELTO 10 mg tablet ONCE a day. XARELTO 15 mg and 20 mg tablets are to be taken with food.

- To prevent major heart related events if you have CAD and/or PAD, the dose is one XARELTO 2.5 mg tablet twice daily. You must also take one 100 mg aspirin tablet once a day. XARELTO 2.5 mg tablets can be taken with or without food. Swallow the tablets preferably with water.
- If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take XARELTO. 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 XARELTO tablet may be given to you through a stomach tube.
- After giving the crushed XARELTO tablet via the stomach tube, you or your carer should flush the tube with water. If you are taking the 15 or 20 mg XARELTO tablet, you should be fed via the stomach tube straight after your dose of XARELTO.
- Follow the instructions provided and use XARELTO until your doctor tells you to stop.

When to take / use XARELTO

- 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 XARELTO 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 XARELTO you should take.
- For prevention of major heart related events if you have CAD and/or PAD, your doctor will tell you when to start treatment with XARELTO 2.5 mg twice daily with aspirin 100 mg once daily. Your doctor will decide how long you must continue treatment.
- 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.

XARELTO has been prescribed to you by your doctor to treat and/or prevent a serious medical condition.

- Try to take the tablet(s) at the same time every day to help you remember.

If you forget to use XARELTO

XARELTO should be used regularly at the same time(s) each day.

- If you are taking one XARELTO 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 XARELTO 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 XARELTO 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 XARELTO 15 mg tablet twice a day as normal, until required.
- If you are taking XARELTO 2.5 mg tablet TWICE a day and have missed a dose, you can take the next dose at the usual time. **Do not take a double dose to make up for a missed dose.**
- **If you have trouble remembering to take your medicine, ask your pharmacist for some hints.**

If you use too much XARELTO

If you think that you have used too much XARELTO, you may need urgent medical attention.

Taking too much XARELTO increases the risk of bleeding.

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 XARELTO?

Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking XARELTO.
- Take XARELTO 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).
- you are prescribed other medications during the course of therapy with XARELTO.
- you become pregnant while you are taking XARELTO.

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

Things you should not do

- Do not take XARELTO 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 XARELTO treats and prevents serious conditions.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how XARELTO 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. 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 the tablets in a cool dry place where the temperature stays below 30°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.

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
Gastrointestinal: <ul style="list-style-type: none"> • diarrhoea, indigestion, or stomach pain 	Speak to your doctor if you have any of

<ul style="list-style-type: none"> • 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>these less serious side effects and they worry you.</p>
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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>Like other similar medicines (anticoagulants), XARELTO 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 XARELTO, however there are measures your health professional can take to control / stop the bleeding.</p> <p>Allergy:</p> <ul style="list-style-type: none"> • 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 <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>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.</p>

<p>Renal-related</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, and heavy bleeding. These symptoms may be related to a condition called anticoagulant-related nephropathy. <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 extensive skin rash associated with fever <p>Injury/wound-related:</p> <ul style="list-style-type: none"> oozing from a surgical wound 	
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Your doctor may need to monitor and conduct blood tests, as XARELTO 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. 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 XARELTO contains

Active ingredient (main ingredient)	rivaroxaban
Other ingredients (inactive ingredients)	microcrystalline cellulose croscarmellose sodium hypromellose lactose monohydrate magnesium stearate sodium lauryl sulfate iron oxide red (10 mg, 15 mg and 20 mg tablets) iron oxide yellow (2.5 mg tablets) macrogol 3350 titanium dioxide
Potential allergens	lactose monohydrate

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

What XARELTO looks like

XARELTO 2.5 mg film-coated tablets are light yellow, round, film-coated tablets marked with the BAYER cross on one side and "2.5" and a triangle on the other side. It is packed in blister packs in cartons of 14, 56, 60, 98 and 100 tablets (AUST R 298198).

XARELTO 10 mg film-coated tablets are light red, round, film-coated tablets marked with the BAYER-cross on one side and "10" and a triangle on the other side. It is packed in blister packs in cartons of 3, 10, 14 15, 28 30 and 100 tablets (AUST R 147400).

XARELTO 15 mg film-coated tablets are red, round, film-coated tablets marked with the BAYER-cross on one side and "15" and a triangle on the other side. It is packed in blister packs in cartons of 7, 14, 28, 42, 84, 98 and 100 tablets (AUST R 181185).

XARELTO 20 mg film-coated tablets are brown- red, round, film-coated tablets marked with the BAYER-cross on one side and "20" and a triangle on the other side. It is packed in blister packs in cartons of 7, 28, 84, 98 and 100 tablets (AUST R 181186).

Not all pack sizes may be marketed.

Who distributes XARELTO

Bayer Australia Ltd
ABN 22 000 138 714
875 Pacific Highway

Pymble NSW 2073

Bayer New Zealand Limited

PO Box 2825

Shortland St

Auckland 1140

New Zealand

Telephone: 0800 233 988

See TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.

See MEDSAFE website (www.medsafe.govt.nz) for latest New Zealand Consumer Medicine Information.

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