

APO-RIVAROXABAN

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 APO-RIVAROXABAN?

APO-RIVAROXABAN contains the active ingredient rivaroxaban. APO-RIVAROXABAN reduces the tendency of blood to form clots and it is used to treat a number of conditions. For more information, see Section [1. Why am I using APO-RIVAROXABAN?](#) in the full CMI.

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

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

3. What if I am taking other medicines?

Some medicines may interfere with APO-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 APO-RIVAROXABAN?

- 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 APO-RIVAROXABAN?](#) in the full CMI.

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

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, surgeon or pharmacist you visit that you are using APO-RIVAROXABAN.• Take APO-RIVAROXABAN exactly as your doctor has prescribed.
Things you should not do	<ul style="list-style-type: none">• Do not take APO-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.
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 APO-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">• Store in a cool dry place where the temperature stays below 25°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 APO-RIVAROXABAN?](#) 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.

Common side effects are headache, diarrhoea, indigestion, stomach pain, constipation, nausea, fever, tiredness, pale skin, breathlessness, pain in the arms or legs, frequent infections and bruising. 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.

APO-RIVAROXABAN

Active ingredient(s): *Rivaroxaban*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using APO-RIVAROXABAN?

APO-RIVAROXABAN contains the active ingredient rivaroxaban.

APO-RIVAROXABAN is an anticoagulant. It works by inhibiting the blood clotting protein called Factor Xa, thus reducing the tendency of blood to form clots.

APO-RIVAROXABAN 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.

APO-RIVAROXABAN 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 APO-RIVAROXABAN?

Warnings

Do not use APO-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.
- 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.

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

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

Check with your doctor if:

- you have any other medical conditions.
- you take any medicines for any other condition.
- you have kidney disease.
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.
- 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 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

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

Pregnancy

Do not use this medicine if you are pregnant or intend to become pregnant.

Women should use a reliable contraceptive while taking APO-RIVAROXABAN.

Breastfeeding

Do not use APO-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.

APO-RIVAROXABAN 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 APO-RIVAROXABAN.**
It is very important to take APO-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 APO-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

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

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 APO-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).

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, he 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 APO-RIVAROXABAN 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 APO-RIVAROXABAN.

4. How do I use APO-RIVAROXABAN?

How much to take / use

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the pharmacist label, ask your doctor or pharmacist for help.

- To prevent clots in your veins after hip or knee replacement operation, the dose is one APO-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 APO-RIVAROXABAN 20 mg tablet once daily.

If your kidneys are not working properly, your doctor may reduce your dose to one APO-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. APO-RIVAROXABAN 15 mg and 20 mg tablets are to be taken with food.

- To treat blood clots in legs and clots in lungs and for preventing blood clots from re-occurring, the usual dose is one APO-RIVAROXABAN 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 6 to 12 months treatment your doctor may decide to continue treatment with either one APO-RIVAROXABAN 20 mg tablet ONCE a day or one APO-RIVAROXABAN 10 mg tablet ONCE a day. APO-RIVAROXABAN 15 mg and 20 mg tablets are to be taken with food.

- To prevent major heart related events with CAD and/or PAD, the dose is one APO-RIVAROXABAN 2.5 mg tablet twice daily. You must also take one 100 mg aspirin tablet once a day. APO-RIVAROXABAN 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 APO-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 APO-RIVAROXABAN tablet may be given to you through a stomach tube.
- After giving the crushed APO-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 APO-RIVAROXABAN tablet, you should be fed via the stomach tube straight after your dose of APO-RIVAROXABAN.
- Follow the instructions provided and use APO-RIVAROXABAN until your doctor tells you to stop.

When to take / use APO-RIVAROXABAN

- 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 APO-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 APO-RIVAROXABAN 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 APO-RIVAROXABAN 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. APO-RIVAROXABAN 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 APO-RIVAROXABAN

APO-RIVAROXABAN should be used regularly at the same time(s) each day.

- If you are taking one APO-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 APO-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 APO-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 APO-RIVAROXABAN 15 mg tablet twice a day as normal, until required. If you are taking APO-RIVAROXABAN 2.5 mg tablet taken 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 APO-RIVAROXABAN

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

Taking too much APO-RIVAROXABAN 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 APO-RIVAROXABAN?

Things you should do

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

Remind any doctor or pharmacist you visit that you are using APO-RIVAROXABAN.

Things you should not do

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

Store the tablets in a cool dry place where the temperature stays 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.

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

Serious side effects

Serious side effects	What to do
Bleeding: <ul style="list-style-type: none"> • prolonged or excessive bleeding from gums, nose etc • heavy menstrual bleeding <p>Like other similar medicines (anticoagulants), APO-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 APO-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.</p> Allergy:	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.

<ul style="list-style-type: none"> signs of allergy 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>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 APO-RIVAROXABAN 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 APO-RIVAROXABAN contains

Active ingredient (main ingredient)	Rivaroxaban
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> microcrystalline cellulose croscarmellose sodium lactose monohydrate hypromellose sodium lauryl sulfate (2.5 mg and 10 mg) magnesium stearate poloxamer (15 mg and 20 mg) OPADRY Complete Film Coating System 03F520333 Yellow (PI 143136) (2.5 mg) OPADRY Complete Film Coating System 03F84770 Pink (PI 109228) (10 mg) OPADRY Complete Film Coating System 03F86990 Brown (PI 109232) (15 mg) OPADRY Complete Film Coating System 03F565072 Brown (PI 143128) (20 mg)
Potential allergens	Lactose monohydrate

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

What APO-RIVAROXABAN looks like

- APO-RIVAROXABAN 2.5 mg film-coated tablets are round shaped, yellow film-coated biconvex tablets debossed with "09" on one side and "L" on the other side. Approximately 4 mm in diameter and 2 mm in thickness. It is packed in blister packs in cartons of 60 tablets.
- APO-RIVAROXABAN 10 mg film-coated tablets are round shaped, pink, film-coated biconvex tablets debossed with "503" on one side and plain on the other side. Approximately 5 mm in diameter and 3 mm in thickness. It is packed in blister packs in cartons of 10, 15 and 30 tablets.
- APO-RIVAROXABAN 15 mg film-coated tablets are round shaped, light brown to brown, film-coated biconvex tablets debossed with "15" on one side and "I" on the other side. Approximately 6 mm in diameter and 3 mm in thickness. It is packed in blister packs in cartons of 28 and 42 tablets.
- APO-RIVAROXABAN 20 mg film-coated tablets are round shaped, brown to dark brown, film-coated biconvex tablets debossed with "20" on one side and "I" on the other side. Approximately 6 mm in diameter and 3.40 mm in thickness. It is packed in blister packs in cartons of 28 tablets.

Who distributes APO-RIVAROXABAN

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne, VIC 3121
Australia
www.arrotex.com.au

Australian Registration Numbers

- 2.5 mg: AUST R 399010
- 10 mg: AUST R 399012
- 15 mg: AUST R 399022
- 20 mg: AUST R 399019

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