

XARELTO[®] (Za-REL-toe)

rivaroxaban

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Xarelto. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Xarelto against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT XARELTO IS USED FOR

The active substance is rivaroxaban. It belongs to a group of medicines called *antithrombotic agents*. It works by inhibiting the blood clotting protein called Factor Xa.

Xarelto is used to prevent blood clots in your veins after a hip or knee replacement operation.

After an operation you are at an increased risk of getting blood clots.

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

Your doctor may have prescribed Xarelto for another reason.

Xarelto is a prescription medicine. It should only be used in adults under medical supervision.

BEFORE YOU TAKE XARELTO

When you must not take it

Do not take Xarelto if you have an allergy to:

- any medicine containing rivaroxaban
- 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.

Do not take Xarelto:

- 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 severely reduced kidney function. Your doctor will know how to determine your kidney function.
- If you are taking medicines for fungal infections e.g. ketoconazole, unless they are only applied to the skin, or itraconazole, voriconazole, or posaconazole
- 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

If you are not sure whether you should start using Xarelto, talk to your doctor or pharmacist.

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

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

Do not take this medicine after the expiry date printed on the pack and blister.

The expiry date is printed on the carton and on each blister after "EXP" (e.g. 11 09 refers to November 2009). The expiry date refers to the last day of that month. If it has expired return it to your pharmacist for disposal.

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

If the packaging is damaged, return it to your pharmacist for disposal.

Before you start to take it
Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- if you have kidney disease

- if you have an increased risk of bleeding such as:
 - bleeding disorders
 - very high blood pressure, not controlled by medical treatment
 - 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.

Your doctor may decide to keep you under closer observation.

If your operation 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.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy,

supermarket or health food shop.

Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while taking Xarelto because its effect may be increased.

Some medicines and Xarelto may interfere with each other. These include:

- other medicines to reduce blood clotting e.g. enoxaparin, clopidogrel or warfarin

These medicines may be affected by Xarelto 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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Tell your doctor if you are taking anti-inflammatory and pain relieving medicines e.g. naproxen, or medicines used for the protection of heart disease e.g. aspirin.

Your doctor may decide to keep you under closer observation.

HOW TO TAKE XARELTO

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.

How much to take

The dose is one tablet (10 mg) once a day. Swallow the tablet preferably with water.

Xarelto can be taken with or without food.

When to take it

Take the first tablet 6 to 10 hours after your operation. Then take a tablet every day until your doctor tells you to stop. Try to take the tablet at the same time every day.

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 exact duration.

If you forget to take it

If you have missed a dose, take it as soon as you remember.

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 have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Australia: 13 11 26 or New Zealand: 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Xarelto. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Taking too much Xarelto increases the risk of bleeding.

WHILE YOU ARE TAKING XARELTO

Things you must 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.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Xarelto.

Tell your doctor if you need to have a surgical or dental procedure.

Tell your doctor that you are using Xarelto, if your doctor is planning for you to have an anaesthetic injection in your back (spinal or epidural injection).

Tell your doctor if other medications are prescribed to you during the course of therapy with Xarelto.

If you become pregnant while you are taking Xarelto, immediately tell your doctor.

Things you must 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

prevents the development of a serious condition.

Things to be careful of

There is no evidence that Xarelto will affect your ability to drive or use machines.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Xarelto.

All medicines have side effects. Sometimes they are serious, most of the time they are not. In serious cases, you may need medical attention.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you experience any of the following side effects and they worry you.

The following list includes the common side effects of your medicine:

- tiredness, pale skin, breathlessness
- feeling sick (nausea)
- long or excessive bleeding following your operation

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.

Like other similar medicines (antithrombotic agents), Xarelto may cause bleeding. In some cases this bleeding may not be obvious.

If any of the following happen, stop taking Xarelto and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- weakness, headache or numbness in the arms and legs
- unexplained swelling or bruising
- diarrhoea, indigestion, or stomach pain
- pain in the arms or legs
- dizziness, fainting
- fast and/or irregular heartbeats
- oozing from the wound
- coughing up blood
- blood in the urine or stool
- prolonged nose bleeds
- 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
- signs of liver problems such as yellowing of the skin and/or eyes (jaundice)

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 that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Check with your doctor or pharmacist as soon as possible if you have any problems while taking Xarelto.

AFTER USING XARELTO

Storage

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.

Store the tablets in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill.

Do not leave it in the car. Heat and damp can destroy some medicines.

Keep out of the reach and sight of children. A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking the tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

PRODUCT DESCRIPTION

What it looks like

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, 15, 30 and 100 tablets. Not all pack sizes may be marketed.

Ingredients

Active ingredient per tablet:

- Xarelto – 10 mg rivaroxaban

Inactive ingredients:

- microcrystalline cellulose
- croscarmellose sodium
- hypromellose
- lactose
- magnesium stearate
- sodium lauryl sulfate
- iron oxide red
- macrogol 3350
- titanium dioxide

Supplier

Made in Germany for:

Bayer Australia Limited
ABN 22 000 138 714
875 Pacific Highway
Pymble NSW 2073

Bayer New Zealand Limited
3 Argus Place, Hillcrest,
North Shore, Auckland 0627
Telephone: 0800 233 988

Australian Registration Number

Xarelto 10 mg - AUST R 147400

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September 2011

See TGA website
(www.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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