



INFORMATION FOR PATIENTS WITH ATRIAL FIBRILLATION

^PXarelto[®] (rivaroxaban) - for the prevention of blood clots
in your brain (stroke) and other blood vessels in your body
if you have atrial fibrillation

 **Xarelto[®]**
rivaroxaban tablet

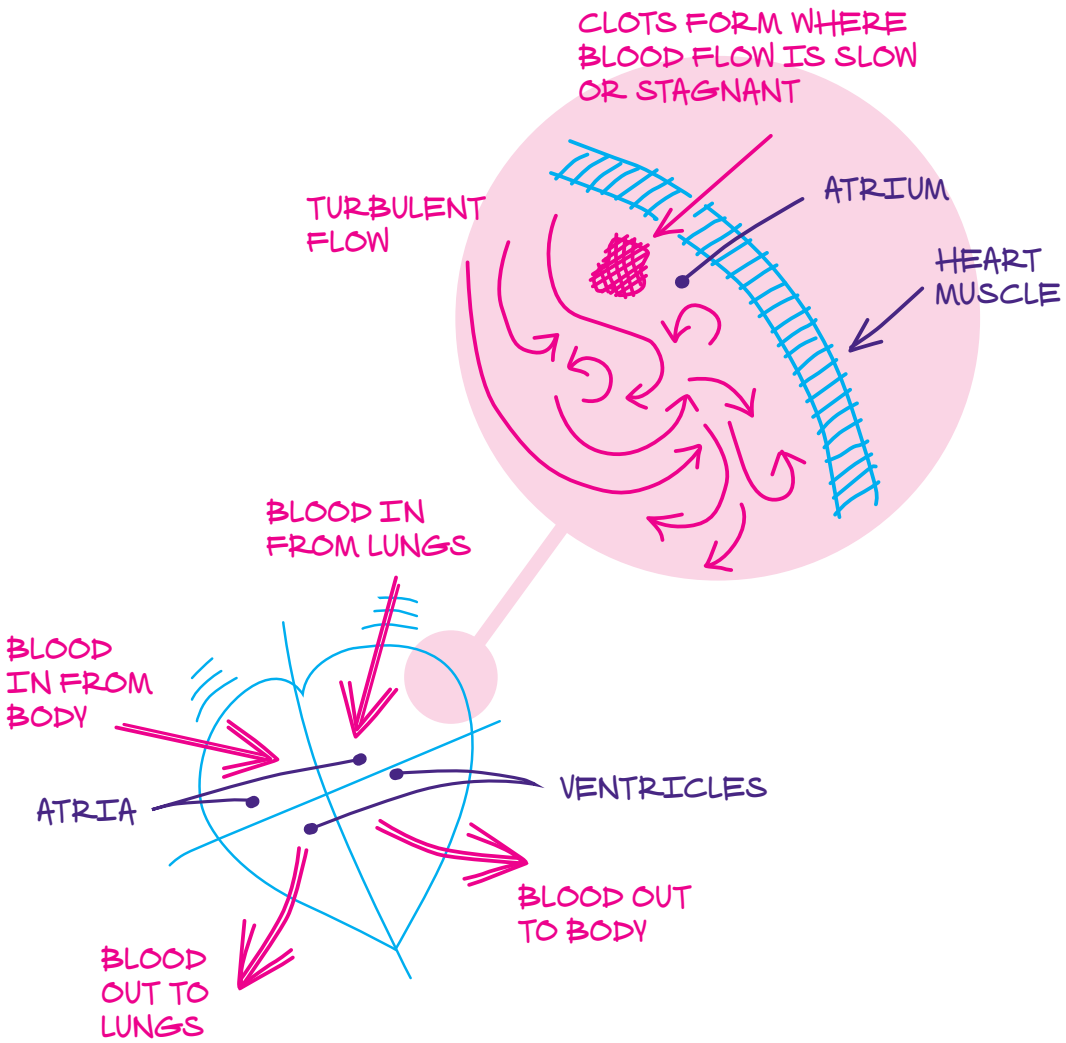
What is atrial fibrillation – and is it serious?

Atrial fibrillation (AF) is an irregular heartbeat. It is caused by a failure of the heart's natural pacemaker that is responsible for coordinating the contractions of the four chambers of the heart. Under normal circumstances the pacemaker first makes the two chambers at the top of the heart (the atria) contract, squeezing blood into the two lower chambers (the ventricles). These in turn are triggered to contract, squeezing blood out into the arteries.

In atrial fibrillation, a malfunction of the pacemaker interrupts this coordinated sequence of contractions causing the atria to twitch erratically – known as fibrillation – and the ventricles to contract more often and irregularly. Not surprisingly the heart works less effectively as a pump in atrial fibrillation, with the result that there are areas within the heart where blood flow is slow or stagnant. Where this happens, blood clots can form and it is these that account for the increased risk of stroke associated with atrial fibrillation.

The exact cause(s) of AF are unclear. In some people, it may develop as a result of underlying conditions such as high blood pressure, structural heart defects, heart infections or inflammation, obesity, or heart attacks. Age is also an important risk factor for AF – it is more common in people over the age of 65.

Some people with AF may not experience any symptoms, while others may experience heart palpitations (rapid thumping in the chest). In other cases, AF can occur in intervals or be continuously present. Whether symptoms are present or not, AF is a condition that should be taken seriously.



Why atrial fibrillation increases your risk of stroke

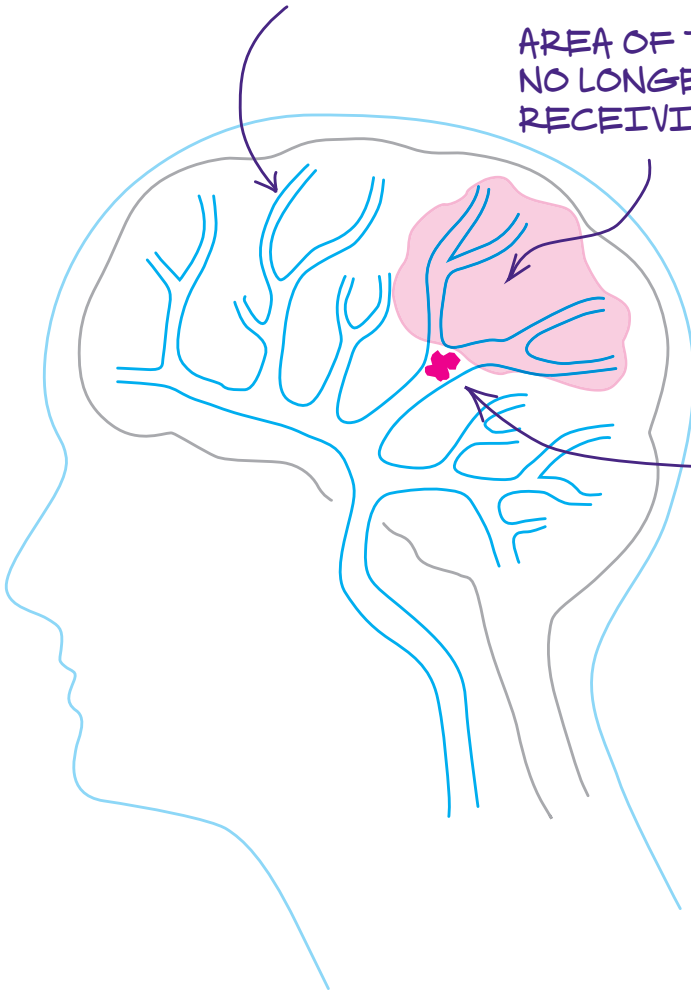
The problem with a blood clot in the heart is that some or all of it can break away and travel along major blood vessels directly into the brain. As these very large blood vessels branch and reduce in size, at some stage the clot or fragment of clot is going to be too large to progress any further and will block the vessel in which it is travelling. This means that the area of the brain downstream can no longer receive blood.

This is what happens in a stroke – or more specifically in an ischemic stroke (meaning one caused by an interruption in the blood supply).

BLOOD VESSELS

AREA OF THE BRAIN
NO LONGER
RECEIVING BLOOD

BLOOD CLOT



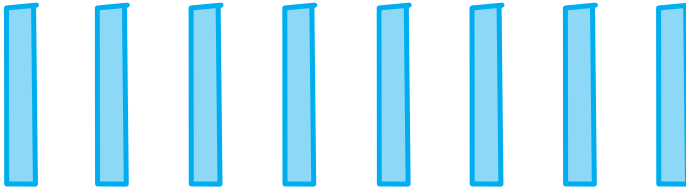
How to avoid a stroke from atrial fibrillation

As you have seen in the preceding pages, if you have atrial fibrillation, you are at an increased risk of stroke due to the formation of blood clots in the heart. So what can be done to reduce this risk?

Clots are formed in a process known as coagulation. This is a complex series of steps that must occur in a specific sequence. Hence, by interrupting one or more of these steps, it is possible to reduce the likelihood of a clot forming and thereby decrease the risk of stroke. The drugs that block the coagulation process in this way are known as anticoagulants.

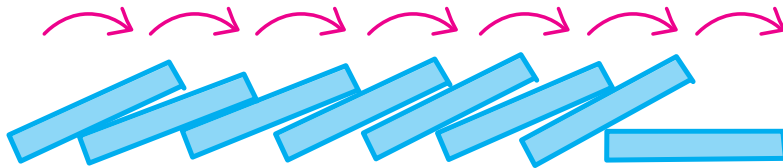
There are different types of anticoagulants; one type is the direct Factor Xa inhibitors.

COAGULATION CASCADE
INACTIVE



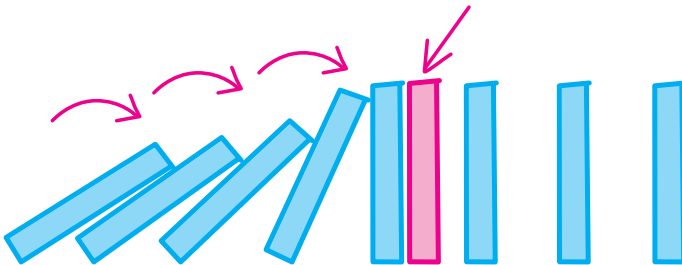
NO CLOT

COAGULATION CASCADE
ACTIVATED



CLOT

COAGULATION CASCADE
BLOCKED BY ANTICOAGULANT



NO CLOT

What is Xarelto®?

The oral anticoagulant that you have been prescribed to reduce the risk of stroke due to atrial fibrillation is called Xarelto®. It is a direct Factor Xa inhibitor. For Xarelto® to work properly, you must take it exactly as prescribed by your doctor.

What is the usual recommended dose of Xarelto®?

The recommended dose of Xarelto® for the prevention of stroke in patients with atrial fibrillation is 20 mg once daily taken with food.

If you have problems with your kidneys, your doctor may have put you on the lower dose of Xarelto® 15 mg, which you should take in just the same way – once a day with food.

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), your doctor may reduce your dose to 15 mg once a day (or to 10 mg once a day if your kidneys are not working properly) in combination with an antiplatelet agent (e.g., clopidogrel).



Actual size, film-coated tablet

How long should I be taking Xarelto®?

Xarelto® is a long-term treatment and you should continue to take it until your physician says otherwise. It is important to continue taking your medication every day.

Do not stop taking Xarelto® without talking to your doctor first, because Xarelto® helps prevent the development of blood clots.

How do I take Xarelto®?

- Take Xarelto® once a day with food
- To help you remember to take your Xarelto®, try to take the tablet at the same time every day
- Swallow the tablet, preferably with water
- **Always follow your doctor's instructions**

If you are currently taking warfarin (another blood thinner taken by mouth), and your doctor has decided Xarelto® is appropriate for you, make sure you ask your doctor exactly when and how best to switch and start taking Xarelto®.

If you have trouble swallowing the tablet **whole**, talk to your doctor about other ways to take it. The tablets may be crushed and mixed with applesauce. Take it right away after you have mixed it. It is important to eat food right after taking a crushed 15 mg or 20 mg tablet.

Alternatively, your doctor may give you the crushed Xarelto® tablet also via a tube.

What if you miss a dose of Xarelto®?

If you miss a dose, take a tablet of Xarelto® as soon as you remember and then carry on as normal the following day with your next tablet. Do not take two tablets on the same day.

What happens if you take too much Xarelto®?

Taking too much Xarelto® increases the risk of bleeding. In case of drug overdose, contact a healthcare practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Possible Side Effects

Like all medicines, Xarelto® can cause side effects, although not everybody gets them. As Xarelto® acts on the blood clotting system, most side effects are related to signs of bruising or bleeding. In some cases bleeding may not be obvious, such as unexplained swelling.

Patients treated with Xarelto® may also experience the following side effects: nausea, vomiting, stomach ache, constipation, diarrhea, indigestion, and decreased general strength and energy.

Information about bleeding:

Possible serious bleeding-related side effects include:

- Bleeding from a surgical wound, an injury, or other medical procedure
- Unexpected bruising
- Reduction in red blood cells which can make your skin pale and cause weakness, tiredness, dizziness, headache, breathlessness, unusually fast heartbeat, or chest pain
- Bleeding:
 - Into the eye
 - From the stomach (could appear as blood in vomit or bloody or blackened stools)
 - From hemorrhoids
 - Under the skin
 - In the urine (red or pink tinge to urine)
- Genital bleeding in post-menopausal women
- Increased or more frequent menstrual bleeding
- Nosebleed lasting more than 5 minutes
- Bleeding from the gums for longer than 5 minutes when brushing teeth
- Bleeding into the brain (sudden, severe, unusual headache)*
- Coughing up blood
- Bleeding into a joint (stiff, sore, hot or painful joint)
- Compartment Syndrome: increased pressure within legs or arms after a bleed, with pain, swelling, numbness or paralysis

This is not a complete list of side effects. If you experience any unexpected effects while taking Xarelto®, talk with your doctor or pharmacist.

*If you experience this symptom, stop taking Xarelto® and seek immediate emergency medical attention.

Other important safety information about Xarelto®

Take special care before and while using Xarelto® if you:

- Have an increased risk of bleeding, as could be the case with conditions 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 blood vessels in the back of your eye (retinopathy)
 - Recent bleeding in your brain (stroke, intracranial, or intracerebral bleeding)
 - Problems with blood vessels in your brain or spinal column
 - A recent operation on your brain, spinal column, or eye
 - A chronic disease of the airways in your lungs causing widening, damage and scarring (bronchiectasis), or a history of bleeding into your lungs
 - If you are older than 75 years of age
- Have a prosthetic heart valve
- Have been told by a doctor that you have antiphospholipid syndrome, a disease which can cause blood clots

Xarelto® is not recommended if you:

- Have severe kidney disease
- Are younger than 18 years of age

Talk to your doctor if you are:

- Having surgery for any reason
- Undergoing a procedure to treat blocked blood vessels in your heart (called a percutaneous coronary intervention – PCI with an insertion of a stent)

- Pregnant, planning on getting pregnant or are breastfeeding
- Taking:
 - Anticoagulants (blood thinners) such as warfarin, heparin or low-molecular-weight heparin (LMWH) including enoxaparin, fondaparinux, bivalirudin, apixaban, dabigatran, edoxaban or anti-platelet agents, such as clopidogrel, ticlopidine, prasugrel, ticagrelor
 - Oral medications to treat fungal infections such as ketoconazole, itraconazole, posaconazole
 - Medications for HIV/AIDS such as ritonavir (Norvir®) and lopinavir/ritonavir (Kaletra®)
 - Anti-inflammatory and pain-relieving medicines including non-steroidal anti-inflammatory drugs (NSAIDs), such as Naprosyn® (naproxen) and Aspirin® (acetylsalicylic acid)
 - Some antibiotics such as clarithromycin
 - Rifampicin
 - Anticonvulsants such as phenytoin, carbamazepine and phenobarbital
 - Medicines to treat depression and/or anxiety (SSRIs, SNRIs)
- You have severe kidney disease since it may increase your chance of bleeding and Xarelto® might not be recommended for you

Lactose is a nonmedicinal ingredient in Xarelto®. Do not take Xarelto® if a doctor has told you that you have one of the following rare hereditary diseases:

- Galactose intolerance
- Lapp lactase deficiency
- Glucose-galactose malabsorption

If you take Xarelto® with NSAIDs or antiplatelet agents such as ASA or clopidogrel or antidepressants/anti-anxiety (SSRIs, SNRIs), you are at an increased risk for bleeding. The use of Xarelto® with prasugrel or ticagrelor is not recommended.

Let's make the most of some lifestyle tips from the Heart and Stroke Foundation of Canada

Living with AF

Healthy lifestyle choices are important in patients with AF, as living with AF is a lifelong journey. The following are some lifestyle tips to keep in mind.

Stay physically active

Staying physically active helps to maintain a healthy weight and lowers blood pressure. Before beginning any new physical activity, check with your doctor to ensure that it is safe and at a reasonable activity level for you.

Eat healthy

Eat a diet that is low in saturated fats, trans fats, and sodium. This type of diet includes vegetables, fruit, fiber, and lean meat. For more information on healthy eating, talk to a nurse, nutritionist or pharmacist for diet tips.

Avoid common triggers of arrhythmia

Common triggers of arrhythmia include smoking and alcohol intake. Therefore, try to limit your alcohol intake, quit smoking and avoid second-hand smoke.

Reduce stress

Reducing stress can help to lower blood pressure. Get involved with activities that can help relieve stress in your life and find ways to manage the stress that is unavoidable.

Go for regular checkups

Ensure that you visit your doctor regularly and have your blood pressure and cholesterol monitored. Ask your doctor for tips to help maintain your quality of life.

Guidance on the use of this brochure

The information presented in this brochure on Xarelto® is for general information only and is intended to support the instructions from your doctor. The brochure cannot replace professional medical care or advice. All decisions regarding your care must be made with a healthcare professional, taking into account your specific medical needs. You should always consult a physician or other healthcare professional to discuss any health problem or medical condition, and to seek further advice.

Further information

To learn more about Xarelto®, atrial fibrillation, and stroke prevention, the following web sites are useful resources:

Xarelto.ca

Visit the Xarelto® patient website for information about Xarelto®, including what it is, how it works and the medical conditions that it is intended to treat.

heartandstroke.com

The Heart and Stroke Foundation website for more information about AF and AF treatments.



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