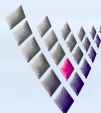




# Information for patients with atrial fibrillation



**Xarelto®**  
rivaroxaban

## 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 orchestrating the coordinated 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 and then the blood is delivered to the body.

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.

CLOTS FORM WHERE  
BLOOD FLOW IS SLOW  
OR STAGNANT

TURBULENT  
FLOW

ATRIUM

HEART  
MUSCLE

BLOOD IN  
FROM LUNGS

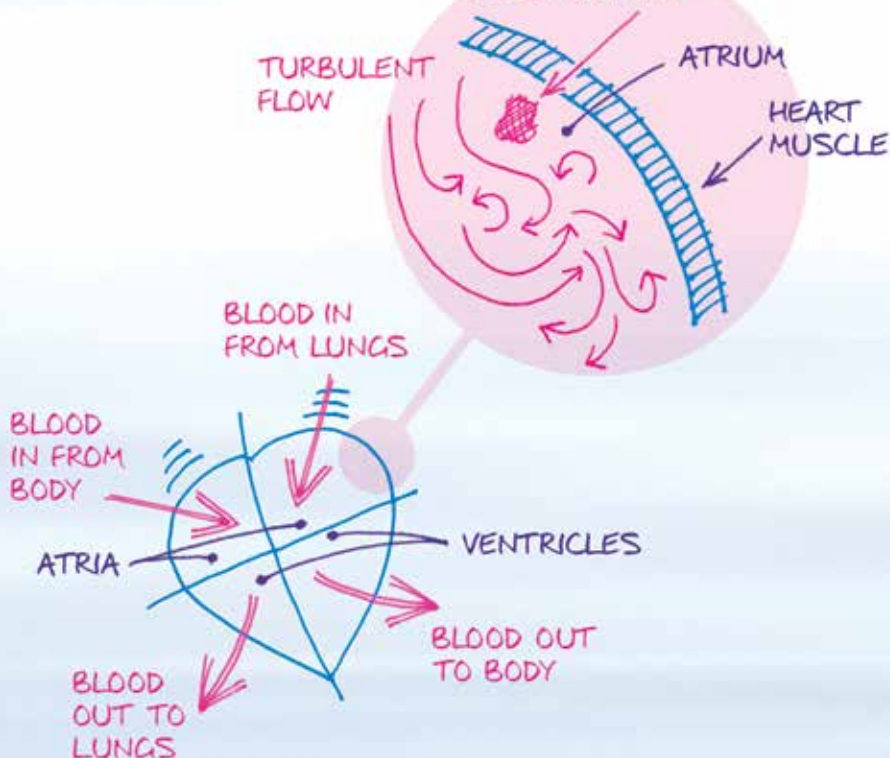
BLOOD  
IN FROM  
BODY

ATRIA

VENTRICLES

BLOOD  
OUT TO  
LUNGS

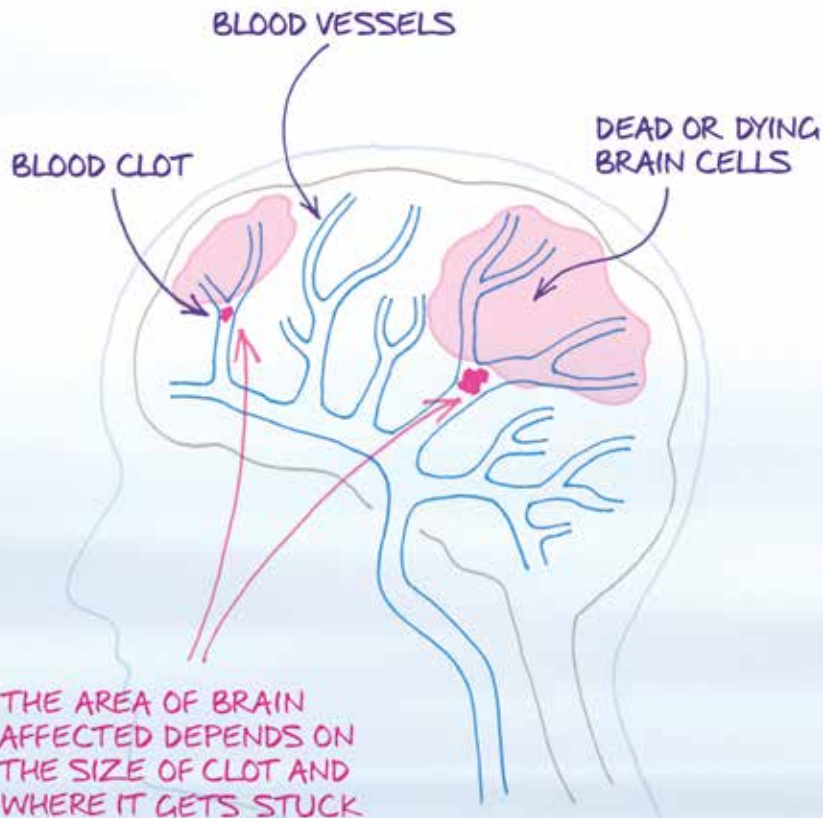
BLOOD OUT  
TO BODY



## Why atrial fibrillation increases your stroke risk

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 piece 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 beyond this blockage or clot can no longer receive the oxygen and nutrients that the blood normally delivers, causing brain cells to stop working and die.

This is what happens in a stroke – or more specifically in an ischaemic stroke (meaning one caused by an interruption in the blood supply). Because clots forming in the heart may be quite big they can block the larger branch vessels that supply extensive areas of the brain. Consequently, strokes arising from atrial fibrillation can be very serious, which is why it is so important to prevent them.



## 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

For many years the most commonly used anticoagulants for stroke prevention in patients with atrial fibrillation have been the vitamin K antagonists. Drugs in this class, such as warfarin, are affected by interactions with a number of common foods and with other drugs. As a result, frequent blood tests are needed to find the appropriate dosage – a process known as monitoring.

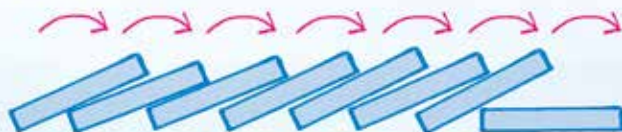
Recently medications have been discovered that can be used in place of vitamin K antagonists, such as warfarin. These medications are less likely to interact with food and other medications you may be taking and as a result don't require frequent monitoring.

COAGULATION CASCADE  
INACTIVE



NO CLOT

COAGULATION CASCADE  
ACTIVATED



CLOT

COAGULATION CASCADE  
BLOCKED BY ANTICOAGULANT



NO CLOT

## How you should take Xarelto®

The tablet you have been prescribed, called Xarelto, is to reduce or minimise the risk of you having a stroke due to the atrial fibrillation, or heart flutter, that you have is called Xarelto®. For Xarelto® to work properly and safely it is important that you follow your doctor's instructions.

### When to take Xarelto®

The recommended dose of Xarelto® for the prevention of stroke in patients with atrial fibrillation is 20 mg once a day. It should be taken at the same time every day 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 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.

If you have been taking warfarin tablets your doctor would have told you not to stop until blood tests confirm that you can begin to take Xarelto® instead. Once you begin taking Xarelto® do not stop again unless told to by your doctor as this may leave you unprotected and at a higher risk of stroke.



## Things to tell your doctor

Like all anticoagulants, bleeding is the most common side-effect associated with Xarelto®. Mostly these are minor, such as a nosebleed. Nevertheless, if you experience any of the following symptoms of bleeding you must tell your doctor immediately:

- ◆ Unusual bruising, nosebleeds, bleeding from your gums, cuts that take a long time to stop bleeding
- ◆ Menstrual flow or vaginal bleeding that is heavier than normal
- ◆ Pink or brown urine; red or black stools
- ◆ Coughing up blood, or vomiting blood – or a substance that looks like coffee grounds.

You should also consult your doctor if you experience sudden pain, swelling or discomfort, or a persistent, out of the ordinary headache, dizziness or weakness.

If you see another health care practitioner, such as another doctor, a dentist, or pharmacist, it is very important that you tell them that you are taking Xarelto®. This is because surgical procedures, including dentistry, could result in excess bleeding. Likewise, you should never take any additional medicine before confirming with the healthcare professional, including pharmacists, that it will not adversely affect the action of Xarelto® – this includes any medicines that you may have obtained without a prescription e.g. arnica, St John's Wort, NSAIDs etc.

## Is there anything else I can do?

The most important thing that you can do to reduce the risk of a stroke from atrial fibrillation is to take an anticoagulant, such as Xarelto®, as instructed by your doctor. In addition, you can improve your general health by making lifestyle changes including reducing caffeine and alcohol intake, losing weight, quitting smoking, and controlling high blood pressure, diabetes or other medical conditions.

Ask your doctor for guidance on what else you can do to help in managing your condition.

### References

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- Global Atlas on Cardiovascular Disease Prevention and Control. Mendis S, Puska P, Norrving B editors. World Health Organization, Geneva 2011.
- Patel MR, Mahaffey KW, Garg J, *et al*. Rivaroxaban versus warfarin in nonvalvular atrial fibrillation. *N Engl J Med* 2011; **365**(10): 883–891.
- Xarelto® 15 and 20 South African Approved Package Insert.

## 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 health care professional, taking into account your specific medical needs. You should always consult a medical doctor or other health care 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 website is a useful resource:

**[Xarelto.co.za](http://Xarelto.co.za)**

The main site for information about Xarelto® – what it is, how it works and the medical conditions that it is intended to treat

For full prescribing information, refer to the package insert approved by the Medicines Authority (MCC).

XARELTO® 15: Each film-coated tablet contains rivaroxaban 15 mg. **South Africa** [S4] Reg. No: 46/8.2/0111;

**Namibia** [NS2] : 12/8.2/0006; [S2] **Botswana:** BOT1302296; **Zimbabwe:** PP10 Reg. 2017/10.2/5363

XARELTO® 20: Each film-coated tablet contains rivaroxaban 20 mg. **South Africa** [S4] Reg. No: 46/8.2/0112;

**Namibia** [NS2] : 12/8.2/0007; [S2] **Botswana:** BOT1302297; **Zimbabwe:** PP10 Reg. 2017/10.2/5364

**PHARMACOLOGICAL CLASSIFICATION:** A.8.2 Anticoagulants. **INDICATIONS:** (1) Prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation (SPAF); (2) Treatment of deep vein thrombosis (DVT) and for the prevention of recurrent deep vein thrombosis (DVT) and pulmonary embolism (PE); (3) Treatment of pulmonary embolism (PE) and for the prevention of recurrent pulmonary embolism (PE) and deep vein thrombosis (DVT). **HCR:** Bayer (Pty) Ltd, Co. Reg. No.: 1968/011192/07, 27 Wrench Road, Isando, 1609. Tel: 011 921 5044 Fax: 011 921 5041.

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