

Xarelto[®]
XPERT

A PATIENT'S GUIDE TO SECONDARY PREVENTION IN ACUTE CORONARY SYNDROME (ACS)



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

Personal Information

Name:

Contact details:

Emergency contact details:

Name of consultant:

GP surgery:

FOREWORD

It is human nature to have questions when we come across or try something new. When something new is related to our health, it is even more important that we have access to the information we need to enable us to feel comfortable.

If you are preparing for treatment with Xarelto (rivaroxaban) to reduce your future risk of having another heart attack, you are likely to be curious as to what it is, how it works and how often you will need to take your medication. Working in collaboration with key patient organisations, Bayer HealthCare have developed *Xarelto Xpert*, helping you understand and better manage your condition. By following our five step plan this leaflet will help you become an 'expert' by:

- **X**ploring your condition
- **P**roviding you with information on Xarelto and how it works
- **E**xplaining how to take Xarelto
- **R**evealing answers to frequently asked questions
- **T**aking you to other useful sources of information

We hope this leaflet helps you to feel confident about taking the next step in your treatment journey with Xarelto. Please read the Patient Information Leaflet for further information on Xarelto.

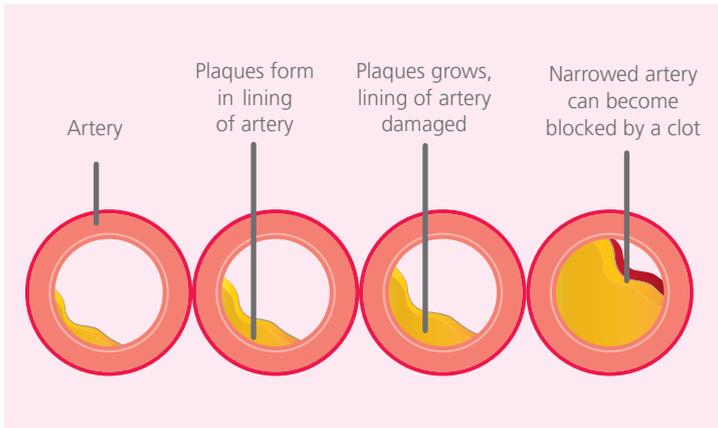


WHAT IS ACUTE CORONARY SYNDROME?

There are an estimated 2.7 million people living with coronary heart disease (CHD) in the UK and 2 million people affected by angina (the most common symptom of coronary heart disease)

Acute **C**oronary **S**yndrome (ACS) is a term used for a group of conditions that includes heart attack and unstable angina, a severe type of chest pain. These conditions occur when there is a sudden restriction of blood flow (ischaemia) in the blood vessels that deliver blood to the heart (coronary arteries). This restriction starves the heart tissue of oxygen and nutrients affecting its ability to function normally. The blood restriction may cause pain and if prolonged may result in damage or death of the heart tissue.





The diagram above shows how atherosclerosis occurs. Plaque builds up inside the arteries supplying blood to the heart

There are different types of ACS which are defined by the level of blood flow restriction and the extent of any resulting damage:

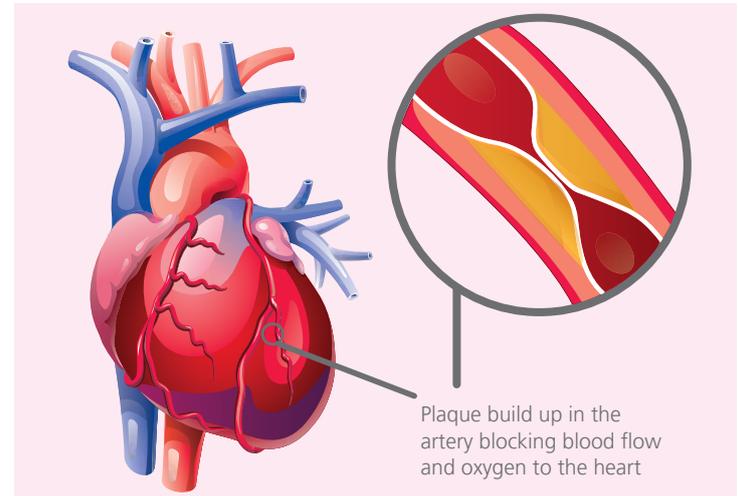
ST segment elevation myocardial infarction (STEMI)

is the most serious type of heart attack. This is caused by a complete blockage of one or more of the arteries supplying blood to the heart. The term 'ST elevation' refers to a change that can be seen on an electrical reading of the heart, an electrocardiogram (ECG). Myocardial infarction or MI, means damage to the heart muscle caused by the lack of blood flow.

Non-ST segment elevation MI (NSTEMI)

occurs when there is a partial blockage of the blood vessels supplying the heart. Like STEMI, this also leads to damage of the heart muscle.

Unstable angina occurs when the blood flow to the heart is restricted but the heart muscle is not permanently damaged as a result of this.



The diagram above demonstrates how a NSTEMI occurs. A partial blockage of the blood vessels supplying the heart, leading to damage of the heart muscle

- Coronary Heart Disease (CHD) is the leading cause of death in the UK and worldwide¹
- CHD is responsible for around 73,000 deaths in the UK each year. About 1 in 6 men and 1 in 10 women die from CHD¹
- ACS is responsible for over 114,000 hospital admissions in the UK each year²

WHAT ARE THE CAUSES AND SYMPTOMS OF ACS?

ACS generally occurs when there has been some narrowing of the blood vessels supplying the heart. The narrowing of the vessels is called coronary heart disease (CHD) and is most commonly caused by atherosclerosis, which is the gradual formation of fatty plaques (atheroma) on the walls of the coronary arteries over a number of years.

Symptoms of ACS include:

- severe chest pain which may feel like a heavy pressure on the chest
- pain that radiates to the jaw, left arm or down both arms
- pain that is similar to stable angina but that lasts more than 15 minutes
- sweating
- feeling sick
- shortness of breath
- minor pain, such as indigestion

There may even be no symptoms at all and this can sometimes occur in the elderly or in people with diabetes.



Understanding the risk factors

Certain people are more likely to develop ACS than others.

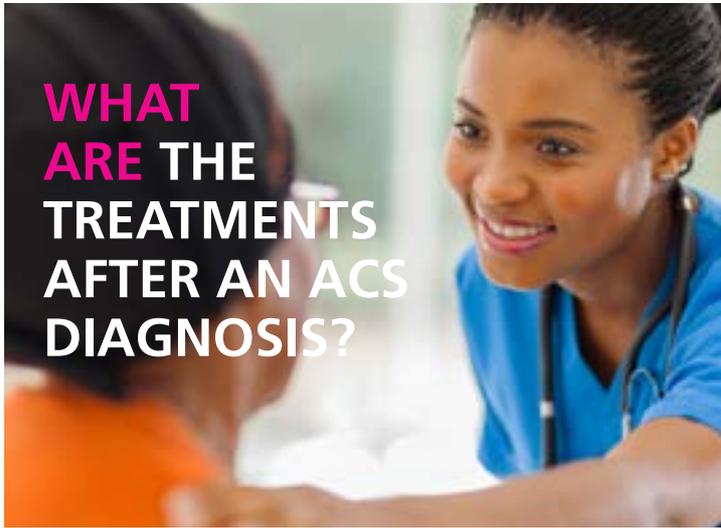
Non-modifiable risk factors include:

- age
- gender
- family history of heart disease or stroke
- ethnic background

Modifiable risk factors include:

- smoking
- high blood pressure
- high cholesterol
- diabetes
- being overweight or obese
- being physically inactive
- poor diet

WHAT ARE THE TREATMENTS AFTER AN ACS DIAGNOSIS?



On being discharged from hospital you should receive additional advice from a healthcare professional on how to reduce your risk factors.

Your immediate treatment for ACS will have depended upon the type of ACS that you were diagnosed with and the time since your symptoms started. This may have included an operation to open up the blood vessels in the heart or medication to break down the blood clots in the blood vessels supplying the heart.

Following your initial diagnosis, you will receive medication to reduce your long-term risk factors for a future heart attack and to reduce other complications resulting from the heart attack. It is likely you will take this medication for the rest of your life.

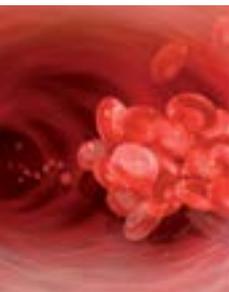


Medications include:

- Beta-blockers which affect heart rate and rhythm
- Anti-platelet agents e.g. aspirin and other anti-platelet drugs
- Blood pressure medication e.g. ACE inhibitors, calcium-channel blockers, diuretics
- Cholesterol lowering agents such as statins

On being discharged from hospital it is likely that you will receive additional advice from a healthcare professional on how to reduce your risk factors. This may include advice on addressing lifestyle factors, such as eating a well-balanced diet, maintaining a healthy weight and leading a healthier and more active lifestyle.

A STEP-BY-STEP GUIDE TO XARELTO



What is Xarelto?

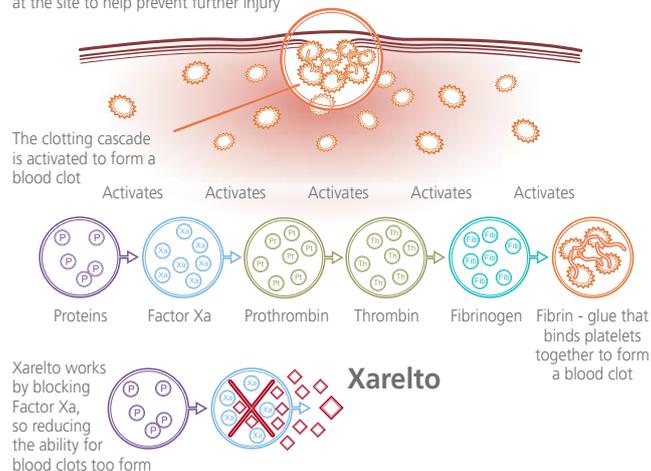
Xarelto is an anticoagulant, which is a type of medication that slows down your body's ability to clot and therefore reduces the likelihood of clots forming in your blood vessels. You have been prescribed Xarelto to help prevent recurrence of your ACS. A 2.5mg Xarelto will not be given to you on its own. Your doctor will also tell you to take antiplatelets such as aspirin or aspirin plus clopidogrel, in conjunction with Xarelto. In addition, you may be prescribed other medications to reduce the risk of heart disease.

How does Xarelto work?

The formation of a blood clot is a natural process (called the clotting cascade) within your body. For example, when you cut yourself, you will see a clot form to stop the bleeding.

Xarelto belongs to a group of medicines called novel oral anticoagulants or NOACs. It works by blocking a specific protein in the blood – Factor Xa ('ten A') – which is known to play a key role in starting the blood clotting cascade process.

When the lining of the blood vessel becomes damaged, platelets are activated at the site to help prevent further injury



Blocking Factor Xa prevents the formation of subsequent proteins that are also involved in the clotting, so reducing the tendency for blood clots to form.

The illustrations above will help you better understand how Xarelto works.

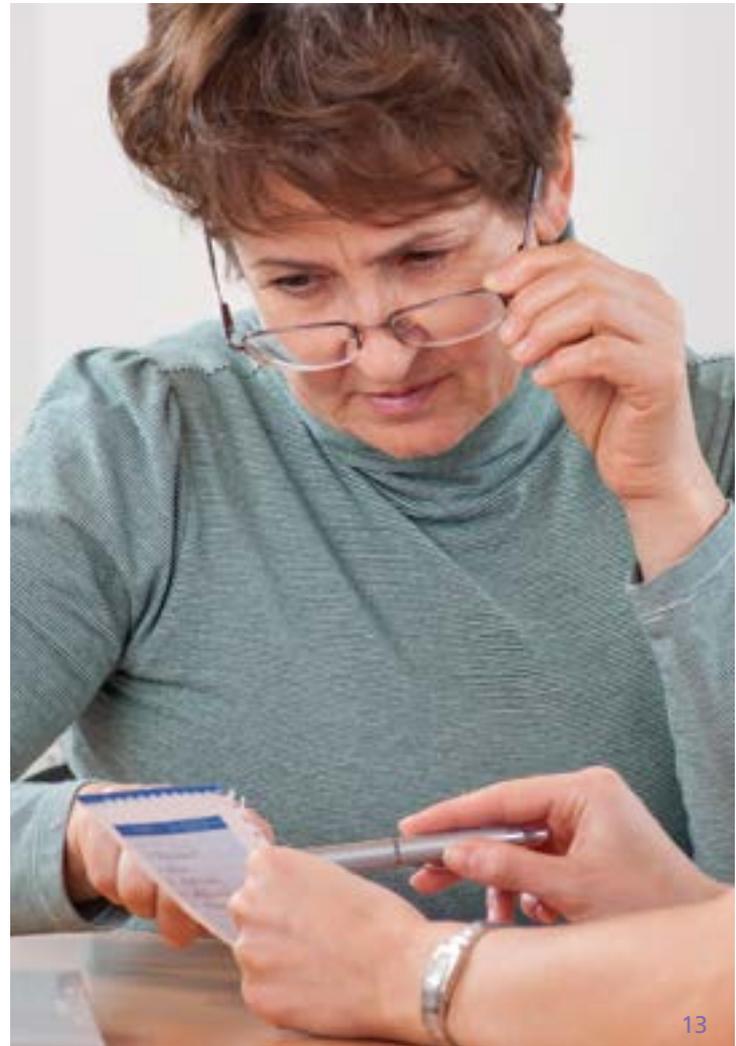
Following a heart attack, substances in the blood such as thrombin may be elevated and this can increase the risk of further blood clots forming in the blood vessels of the heart. Xarelto can interrupt the blood coagulation cascade, inhibiting thrombin formation and the development of further thrombi (blood clots). In this manner, Xarelto can reduce the chance of further heart attacks from occurring.

Xarelto is taken orally (via the mouth) and the usual dose for the prevention of atherosclerotic events after ACS is one 2.5mg tablet twice a day.

How is Xarelto taken?

Xarelto is taken orally (via the mouth) and the usual dose for the prevention of atherosclerotic events after ACS is one 2.5mg tablet twice a day. The tablets should be swallowed with water, and can be taken with or without a meal. If you have problems swallowing a whole tablet you may crush the tablet and dissolve it in water, or mix it into an apple puree immediately before use and take it orally. Before doing so, please seek guidance from your healthcare professional to ensure Xarelto is being administered correctly. Try to take the tablets at the same time each day to help you remember them.

Xarelto is used to treat different patients for different reasons. Another person prescribed Xarelto may take a different dose from you. Always take Xarelto exactly as your doctor has told you and check with your doctor or pharmacist if you are unsure of your correct dose.



YOUR XARELTO QUESTIONS ANSWERED

What do I do if I miss a dose of 2.5mg Xarelto?

If you have missed a dose of Xarelto continue with your regular 2.5mg dose at the next scheduled time. The dose should not be doubled to make up for a missed dose. Continue with the regular 2.5mg twice daily intake on the following day.

What do I do if I take too much 2.5mg Xarelto?

If you have taken too many Xarelto tablets contact your doctor immediately as taking too many may increase your risk of bleeding.

How long will I be treated with 2.5mg Xarelto for?

Length of treatment with Xarelto is based on an individual assessment of your risk factors and the benefits of long term preventative treatment. Your doctor will discuss this with you and together agree the most appropriate length of treatment.

What are the most common side effects of Xarelto?

Like all medicines, Xarelto can cause side effects. We are all different these will vary from one person to another. However these side effects may also be caused by the other antiplatelet agents that you may be taking.

Xarelto is an anticoagulant medicine that slows down your body's ability to clot, a common side effect is an increased risk of bleeding – either external, visible blood loss or internal bleeding inside the body.

Symptoms of internal bleeding include:

- pain
- swelling or discomfort
- headache, dizziness or weakness
- unusual bruising, nosebleeds, bleeding of gums, cuts that take a long time to stop bleeding

- menstrual flow or vaginal bleeding that is heavier than normal
- blood in your urine which may be pink or brown, red or black stools
- coughing up blood, or vomiting blood or material that looks like coffee grounds.

Why am I being prescribed 2.5mg Xarelto twice a day?

You are being prescribed 2.5mg Xarelto to specifically prevent atherothrombotic events, characterised by a sudden, unpredictable, atherosclerotic plaque disruption (rupture or erosion), and thrombus (blood clot) formation after an ACS. In addition to Xarelto 2.5 mg, you should also take a daily dose of 75-100 mg Acetylsalicylic Acid (ASA) or a daily dose of ASA in addition to either a daily dose of 75 mg clopidogrel or a standard daily dose of ticlopidine.

Will I bleed more if I have a cut whilst taking Xarelto?

As Xarelto slows down your body's ability to clot, bleeding is a common side effect. However, if you experience excessive bleeding, tell your doctor immediately.

What happens if I need to have dental treatment or an operation whilst I am taking Xarelto?

As Xarelto may increase your risk of bleeding it is important that you tell your dentist or doctor that you are taking Xarelto before any dental treatment or operation. A patient alert card is provided at the back of this leaflet which you should carry with you at all times and show in advance of any dental treatment or operations to ensure you are treated appropriately.

YOUR XARELTO QUESTIONS ANSWERED

If you have any symptoms of bleeding, tell your doctor or visit your nearest A&E department immediately so that you can be monitored and have your treatment assessed.

For a full list of possible side effects, please refer to the Patient Information Leaflet provided with your Xarelto tablets. If you think you are experiencing side effects from Xarelto at any time, contact your doctor or pharmacist immediately for advice.

Will I be monitored during treatment with Xarelto?

Xarelto is not known to be affected by food or drink, like other anticoagulation medicines such as warfarin, and you do not need to be monitored with regular blood tests. However, it is important that you attend regular follow-up visits with your doctor to assess and manage your condition and monitor your treatment with Xarelto.

Can I take other medications with Xarelto?

Tell your doctor if you are taking other medications, even medicines obtained without a prescription (e.g. herbal remedies, vitamins, over-the-counter medicines).

Do I need to avoid certain types of food when using Xarelto?

No. Xarelto has no known food interactions.

Can I drink alcohol whilst taking Xarelto?

Xarelto does not interact with alcohol. However, you should always drink in moderation and stay within the recommended guidelines.

Can I take Xarelto if I am intolerant to some sugars?

Xarelto contains lactose and you should speak to your doctor if you have a known intolerance to some sugars before taking it.

Can I take Xarelto if I am pregnant or breastfeeding?

It is important that you discuss this with your doctor as you must not take Xarelto if you are pregnant or breastfeeding. If there is a chance that you could become pregnant, it is essential that you use a reliable contraceptive while you are taking Xarelto. If you become pregnant while you are using Xarelto, inform your doctor immediately, who will discuss your treatment options.

Can I drive or operate machinery whilst taking Xarelto?

Xarelto may cause headaches or dizziness. If you experience these symptoms you should not drive or use machinery.

How is Xarelto stored?

Xarelto does not have any special storage conditions, however, keep it out of the reach and sight of children and do not use Xarelto after the expiry date (which is provided on the pack).



If you still have questions about the use of Xarelto please ask your doctor who will be able to answer these and provide you with more information as appropriate.



HOW TO USE YOUR XARELTO PATIENT ALERT CARD

In the unlikely event of an emergency, a doctor treating you will need to be made aware of the existing medications you are on so that you can be cared for appropriately. The attached alert card has been designed to make the doctor aware that you are receiving treatment with Xarelto. Please carry this with you at all times. In addition, please show your card in advance of any dental treatment or operation to ensure you are treated appropriately.

In case of further questions, please contact the initiating hospital:

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USEFUL SOURCES OF INFORMATION

To find out more about managing your ACS please visit the following independent websites and organisations:

Anticoagulation Europe

Tel: 020 8289 6875

Email: admin@anticoagulationeurope.org

Website: <http://www.anticoagulationeurope.org/>

The British Cardiac Patients Association (BCPA)

Tel: 01223 846 845

NHS Choices – Healthy Hearts

<http://www.nhs.uk/Livewell/Healthyhearts/Pages/Healthyheartshome.aspx>



This guide has been developed as a service to patients by Bayer

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