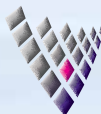
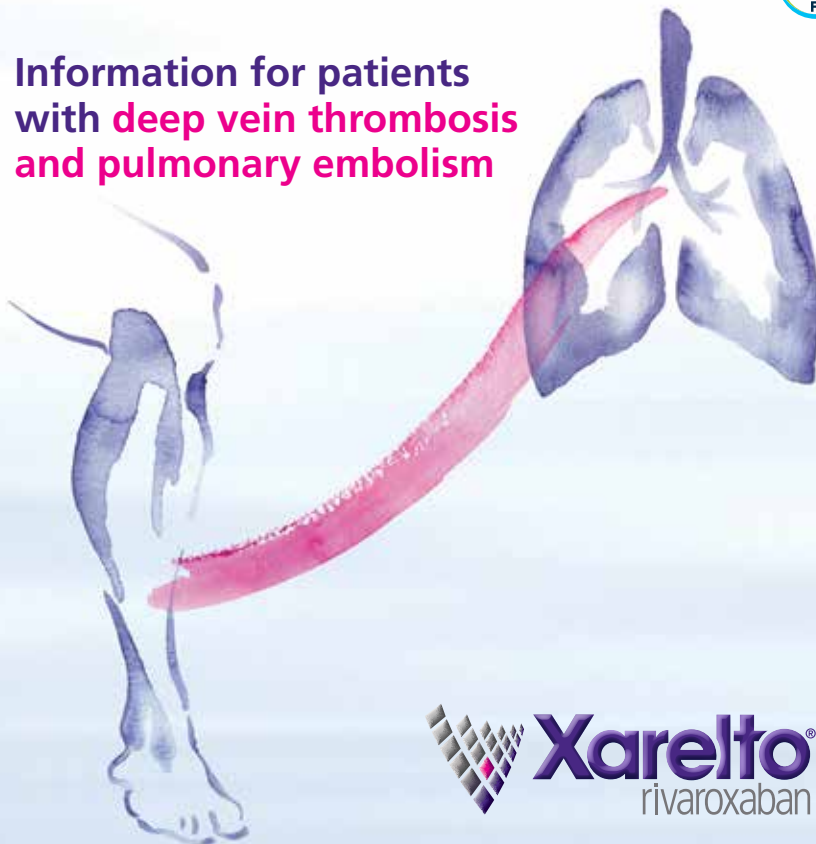




Information for patients
with **deep vein thrombosis**
and **pulmonary embolism**

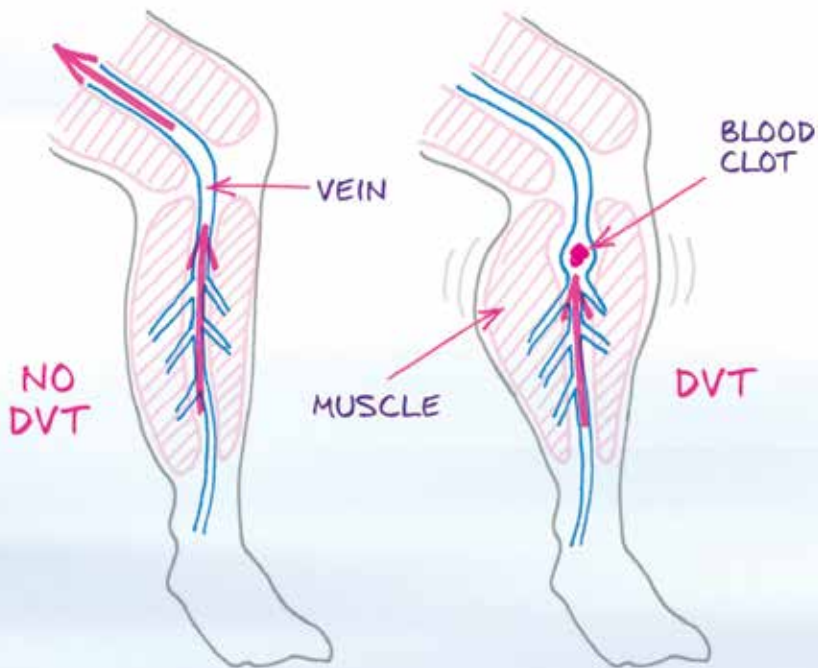


Xarelto®
rivaroxaban

Deep vein thrombosis explained

A deep vein thrombosis (DVT) is a blood clot that has formed in one of the veins that lie deep inside the muscles of the leg. Most of the time, the ability of blood to clot is rather useful; it forms a plug that saves us from bleeding to death from a minor wound. However, sometimes the clotting process – known as coagulation – is triggered inappropriately, and a clot forms inside a vein when it is not needed to prevent blood loss. Well known risk factors for such unwanted coagulation include surgery, cancer, immobility, obesity, smoking and pregnancy.

Whatever the cause, a DVT can become large enough to act as a dam in the affected vein, trapping blood and leading to the classic symptoms of swelling of the leg and pain. But this is not the worst of it. Some or all of the clot can break away from where it was formed and travel out into the lungs via the heart, leading to a pulmonary embolism. What this is and how it happens is explained on the next page.



NORMALLY BLOOD
RETURNS TO THE HEART
IN VEINS DEEP WITHIN THE
MUSCLES OF THE LEG

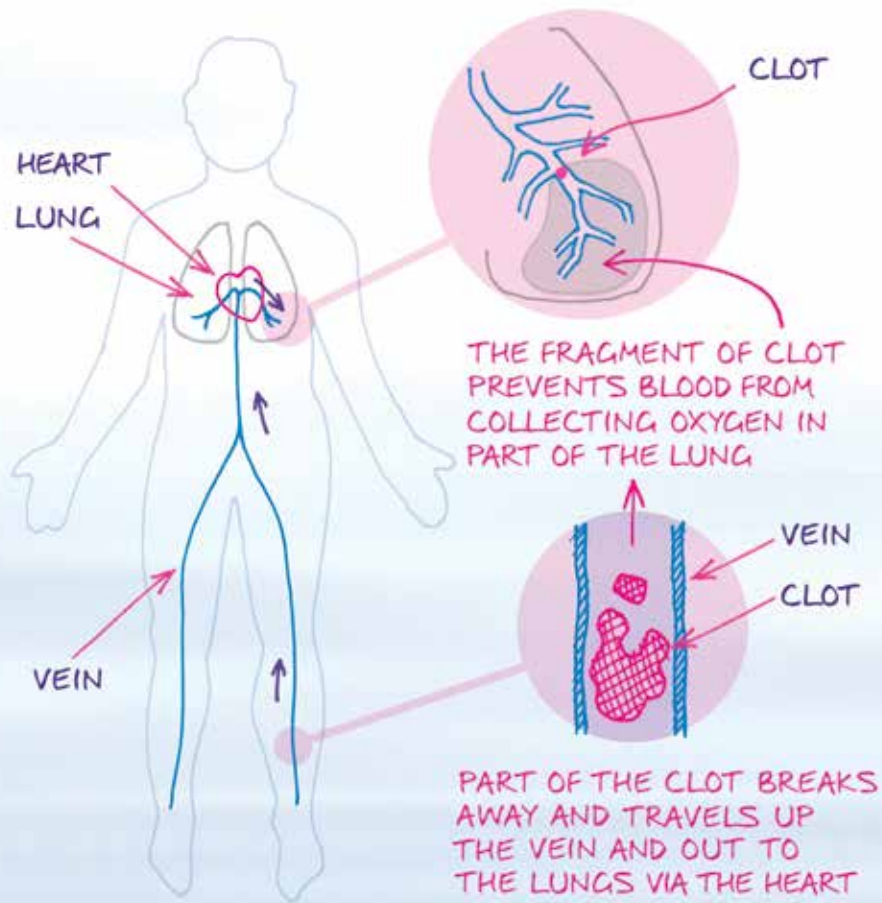
IN DVT BLOOD
BACKS UP BEHIND
THE CLOT CAUSING
SWELLING AND PAIN

How a deep vein thrombosis (DVT) can cause a pulmonary embolism (PE)

A pulmonary embolism (PE) is one of the most serious consequences of a deep vein thrombosis (DVT), although it is possible to have a pulmonary embolism without experiencing a prior DVT. When a PE occurs following a DVT it begins with either the whole clot, or more commonly part of the clot, breaking away from where it was formed in the leg vein and traveling onwards and upwards into the heart and then out into the lungs. Most of this journey is through rather large blood vessels, but once in the lungs these rapidly reduce in size as they branch and divide to cover the large surface area of each lung that is needed to capture life-giving oxygen.

Inevitably the clot reaches a blood vessel too small to permit further passage, preventing blood from reaching the area of lung that it serves. This effectively turns off the oxygen supply from part of the lung and is then called a pulmonary embolism. A pulmonary embolism can be fatal so it is very important that you are alert to the symptoms, which can include shortness of breath, chest pain, coughing up blood and/or a racing heart. This is also why it is so important that a DVT is treated quickly and effectively, and thereafter you receive adequate protection against any recurrence of either a DVT or PE. Treatment is especially important if you have already had a PE in order to prevent recurrence.

If you think that you are experiencing the symptoms of a PE, you should contact your doctor immediately



Treating deep vein thrombosis (DVT) / pulmonary embolism (PE) and preventing recurrence

The treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) is aimed at preventing the formation of any further clots while providing the right conditions for the body's natural processes to break down the existing clot. Medicines used to treat blood clots are called anticoagulants – because they act on the coagulation process. This is a complex series of steps that occurs in a specific sequence. Hence, by interrupting one or more of these steps it is possible to reduce the likelihood of a clot forming.

For many years the standard treatment of DVT and PE has been daily injections of one type of anticoagulant called a heparin, followed by tablets of a second anticoagulant called a vitamin K antagonist. This standard treatment for DVT and PE is highly effective, but it does have a number of drawbacks. These include the need for injections, and the interaction of vitamin K antagonists (such as warfarin) with a number of common foods and with other drugs. Frequent blood tests are needed throughout the whole treatment period to find the appropriate dosage of vitamin K antagonist – a process known as monitoring.

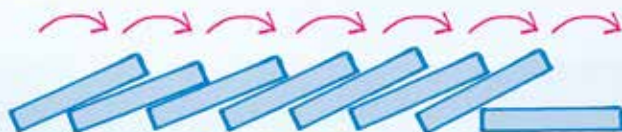
You have been prescribed a oral anticoagulant that is a single drug alternative to the current dual-drug approach of heparin injections and vitamin K antagonist tablets. This new drug is largely free from interactions, and consequently does not require monitoring.

COAGULATION CASCADE
INACTIVE



NO CLOT

COAGULATION CASCADE
ACTIVATED



CLOT

COAGULATION CASCADE
BLOCKED BY ANTICOAGULANT



NO CLOT

How you should take Xarelto®

The oral anticoagulant that you have been prescribed to treat your deep vein thrombosis (DVT) or pulmonary embolism (PE) and to prevent the recurrence of a DVT or PE is called Xarelto®. For Xarelto® to work properly, you must take it exactly as prescribed by your doctor.

Xarelto® should always be taken with food. The recommended dose of Xarelto® for the initial treatment of acute DVT or PE is 15 mg twice daily for the first three weeks, followed by 20 mg once daily for the continued treatment and prevention of recurrent DVT and PE. Your doctor may reduce the dose under certain circumstances.

If you miss a dose during the first three weeks, immediately take a 15 mg tablet to ensure that you receive the correct daily dose of 30 mg of Xarelto®. If you have missed both doses, then take two 15 mg tablets at once then carry on as normal starting the following day, taking 15 mg twice daily. If you miss a dose when you are only taking one 20 mg tablet per day (or the reduced dose prescribed by your doctor), take one immediately and then carry on as normal the following day with your next tablet.

If you have been taking warfarin tablets, your doctor would tell when you can begin to take Xarelto® instead. Once you begin taking Xarelto® do not stop again unless told to do so by your doctor.

Things to tell your doctor

As with all anticoagulants, bleeding is the most common side effect associated with Xarelto®. Mostly this is minor, such as a nose bleed. Nevertheless, if you experience any of the following signs or 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 practitioner 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 make the treatment of your DVT or PE as effective as possible, and to prevent recurrence, is to take Xarelto® as instructed by your doctor. However, you can also help to prevent the recurrence of this serious condition by avoiding the risk factors for deep vein thrombosis, and in particular long periods of immobility, such as when embarking on long-distance travel. When on a long journey try to move about when possible and avoid sitting with crossed legs. General lifestyle changes that can reduce the risk of DVT include losing weight, quitting smoking, and drinking less alcohol.

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

References

- Goldhaber SZ, Morrision RB. Pulmonary Embolism and Deep Vein Thrombosis. *Circulation* 2002; **106**: 1436–38
- Spencer FA, Emery C, Lessard D, et al. The Worcester Venous Thromboembolism study: a population-based study of the clinical epidemiology of venous thromboembolism. *J Gen Intern Med*. 2006; **21**: 722–27
- Goldhaber SZ. Pulmonary Embolism. *N Engl J Med* 1998; **339**: 93–104
- Prandoni P, Lensing AW, Cogo A, et al. The long-term clinical course of acute deep venous thrombosis. *Ann Intern Med* 1996; 125(1): 1–7
- 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®, the following web sites are useful resources:

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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