

This booklet is only to be given to patients who have been prescribed Eliquis.

ELIQUIS[®] (apixaban) for patients with deep vein thrombosis or pulmonary embolism

Patient Information Booklet

Please always read the patient information leaflet in your ELIQUIS package.

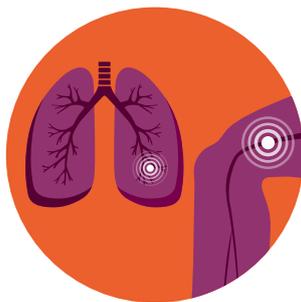


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Introduction

If you are reading this booklet, you have been told by your doctor that you have a condition called venous thromboembolism (or VTE, for short). This might mean that you have a deep vein thrombosis (DVT), a pulmonary embolism (PE), or both.

Your doctor has prescribed ELIQUIS® (name of the active ingredient, apixaban), a type of medication known as a direct-acting oral anticoagulant (or DOAC). ELIQUIS is given to treat your VTE, and help prevent another one from occurring.

This booklet aims to cover key information you may find useful if you have been prescribed ELIQUIS. It is intended to complement, but not replace, the information provided by your healthcare team.

As with any medication you are prescribed, you should also **read the Patient Information Leaflet thoroughly for a full overview.** It is provided inside your pack of ELIQUIS.

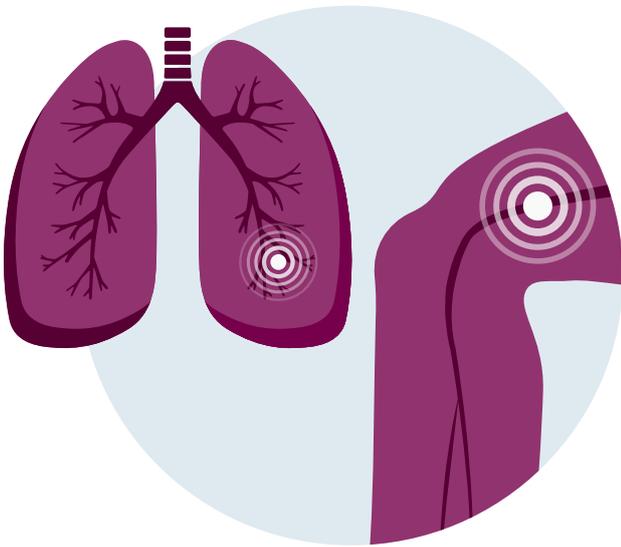


In this extraordinary time, your health remains a priority. It is important to protect yourself against potential exposure to COVID-19 and minimise your chance of catching the virus that causes this disease.

Remember, you have a team of dedicated healthcare professionals trained to help you with your condition and treatment and to offer support. During this pandemic, you may be able to speak with your healthcare team over the phone, or via online video consultation tools, about any concerns or questions you may have.



About VTE

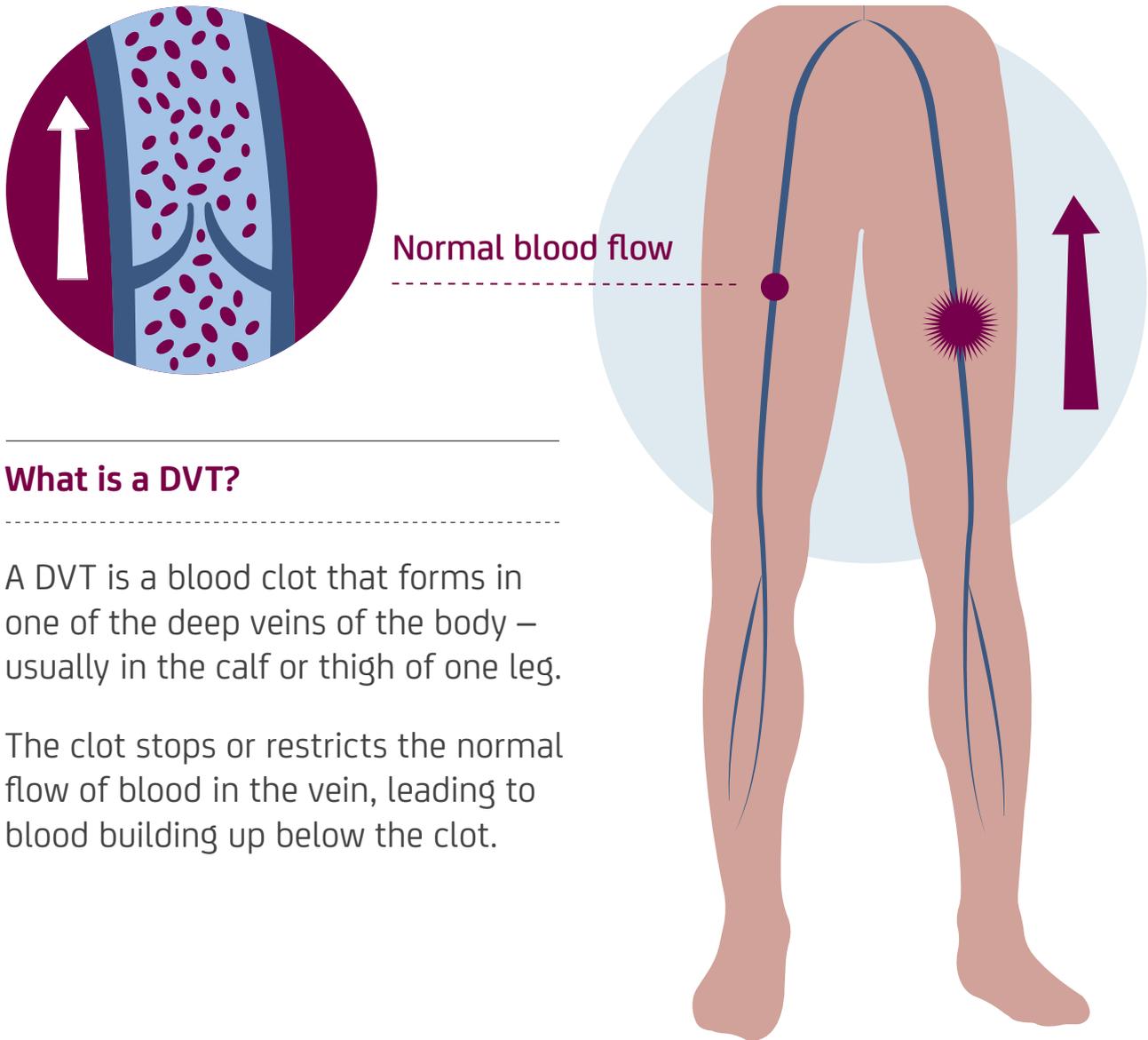


Both of these conditions result when a blood clot (sometimes known as a *thrombus*) blocks a key blood vessel. They are potentially serious conditions but can be treated – the key is to act quickly if you spot the symptoms.

What is VTE?

After learning that you have a venous thromboembolism (VTE), you may be wondering what this condition is. VTE is a term that covers two related conditions – deep vein thrombosis (DVT), and pulmonary embolism (PE).

If you have had a DVT or PE, you are not alone. VTE is a fairly common condition, and approximately 1 in 20 people will have a VTE in their lifetime.



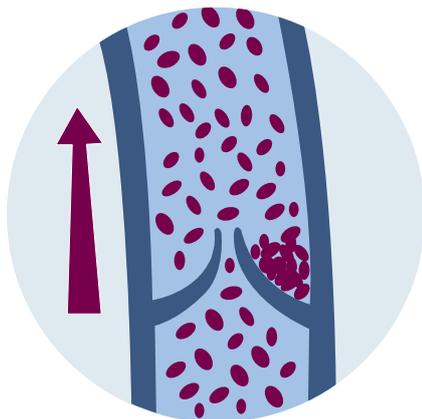
What is a DVT?

A DVT is a blood clot that forms in one of the deep veins of the body – usually in the calf or thigh of one leg.

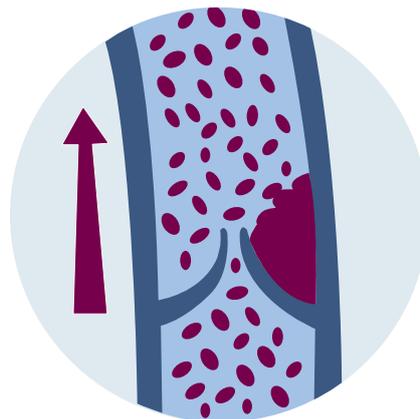
The clot stops or restricts the normal flow of blood in the vein, leading to blood building up below the clot.

DVT formation

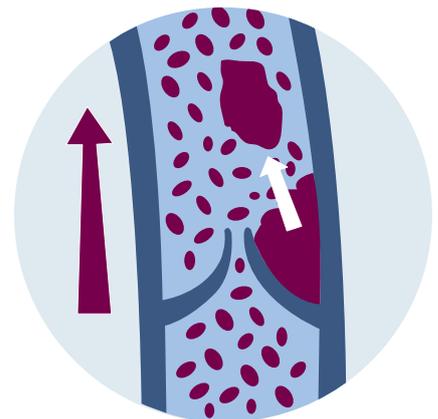
Stage 1



Stage 2



Stage 3





The most common signs of a DVT are:

- A cramp-like pain or soreness, often in the calf
- Swelling, usually affecting only one limb
- Change in skin colour (red / discoloured / darkened) or warmth on the affected limb



What does a DVT feel like?

Some people with DVT do not experience any symptoms. If you do have symptoms, they may start suddenly, or they may appear slowly over days and weeks.

DVTs can be difficult to diagnose, as the symptoms are non-specific and are similar to those of muscle pain or soreness from cramp or a muscle strain.

However, if this cramp-like pain is accompanied by swelling, warmth, or a change in skin colour, it is likely to be a DVT.

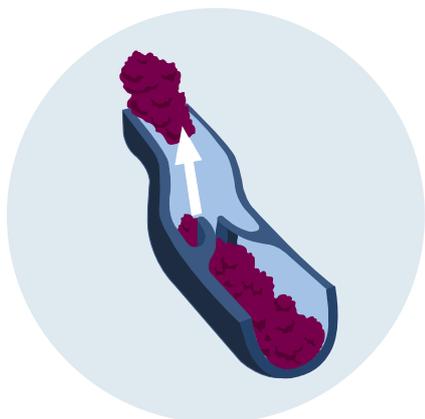
! If you are having these symptoms, visit your doctor as, if untreated, a DVT may lead to a PE.

What is a PE?

A PE occurs when a blood vessel in the lungs gets blocked by a blood clot or part of a clot that has broken loose from a DVT and travelled through the bloodstream and into the lungs (an 'embolus').

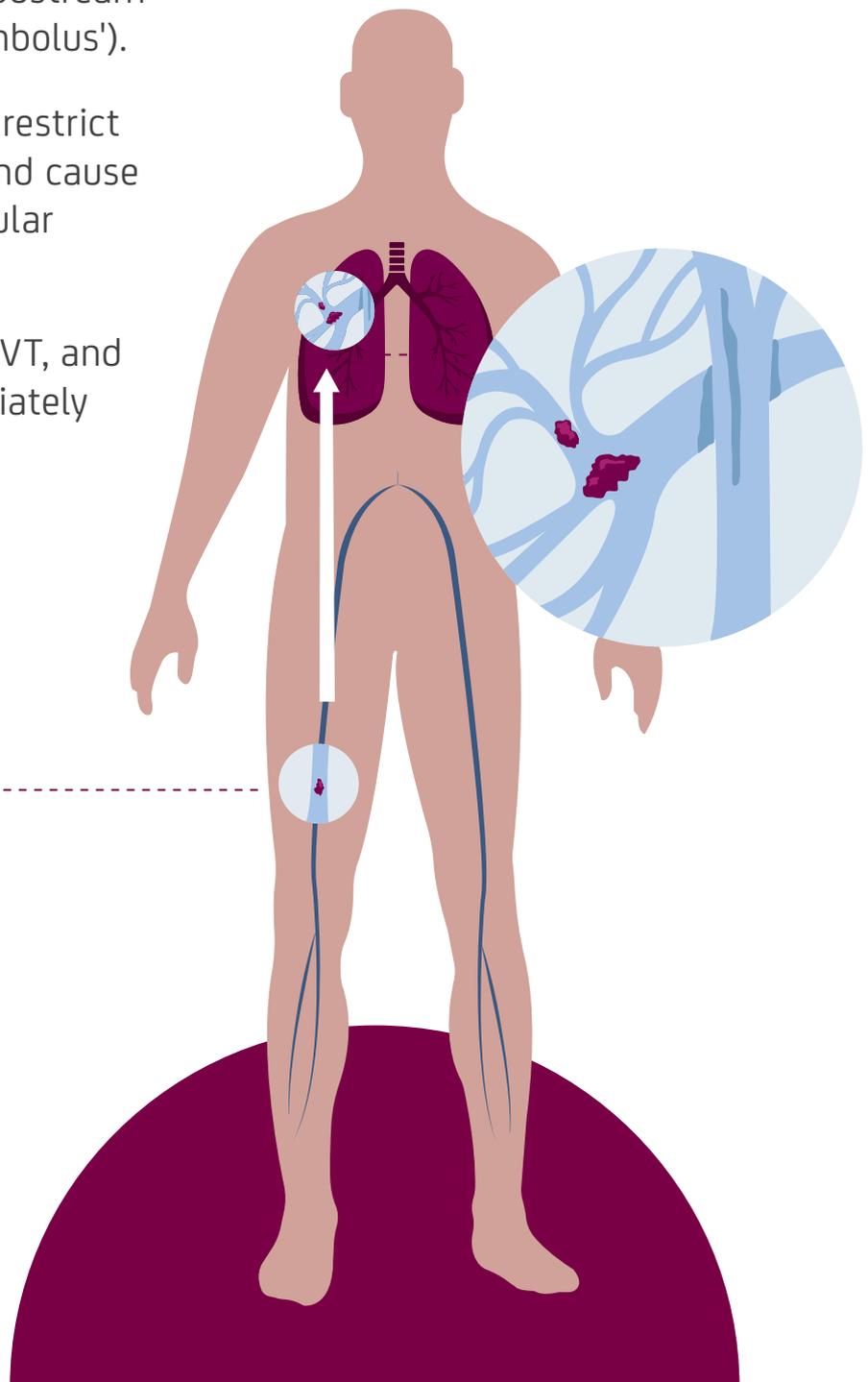
If the clot is large, it may restrict blood flow to the lungs and cause breathing and cardiovascular difficulties.

PE is more serious than DVT, and can be fatal if not immediately diagnosed and treated.



What does a PE feel like?

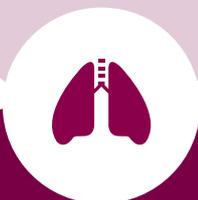
As with DVT, the symptoms of PE are non-specific and depend on the severity of the blockage.





Symptoms of PE can include:

- Shortness of breath, or difficulty breathing
- Cough (with or without blood-stained mucus)
- Chest pain or discomfort
- Anxiety
- Dizziness
- A faster than normal or irregular heartbeat, or low blood pressure



You should be aware that these symptoms can be similar to the symptoms of other conditions, for example, pneumonia or heart attack.

If you are experiencing any of these symptoms, it is very important that you visit your doctor to seek advice. Bear in mind that you may not need to go and see the doctor in person – many consultations are now being held over the phone or via a computer.

Your healthcare team will discuss the best option for you to help keep you safe and reduce your risk of contracting the coronavirus from face-to-face contact.



If you are having chest pain or difficulty breathing, please SEEK IMMEDIATE MEDICAL ATTENTION.

What causes a VTE?

Anyone can develop a VTE, but there are some things that increase the risk of a VTE occurring. These are called 'risk factors'. The more risk factors you have, the greater your chance is of having a VTE.

DVT is generally caused by a combination of underlying medical conditions or situations that increase the chance of a DVT occurring, for example:

Slow blood flow due to lack of mobility because of:

- Severe medical illness
- Hospitalisation
- Being confined to bed
- Long-haul travel
- Sedentary lifestyle

A tendency for blood to clot quickly due to:

- Inherited conditions
- Increased oestrogen levels, such as in pregnancy and up to 6 weeks after birth, or if undergoing hormone replacement therapy or oral contraception

Injury or inflammation

- Recent major surgery or injury
- Inflammatory bowel disease (this is for deep vein thrombosis only)

Certain chronic medical conditions

- Heart, lung, or kidney disease
- Cancer and its treatments

Other factors:

- Personal history of clotting problems or previous DVT / PE
- Family history of DVT / PE
- Increasing age (over 60 years)
- Smoking
- Being overweight or obese

Can a VTE happen again?

If you have had a VTE, your chance of having another one is higher than somebody who has never had one. This is called 'recurrent' VTE.

The risk of recurrence is:

- About **3%** per year in people who no longer have risk factors for VTE (e.g. have recovered from surgery or who no longer travel long-haul)
- About **10%** per year (or more) in people who still have risk factors (e.g. cancer or an inherited disorder), or whose cause of VTE was unknown

The risk of recurrence varies for each person, based upon your individual risk factors.



As early detection is important for reducing your risk, recognising the signs and symptoms of a new or a recurrent VTE – and getting prompt treatment – are vital.

How can a VTE be treated?

Your doctor has prescribed you ELIQUIS® (apixaban), which is a type of medicine known as an ‘anticoagulant’, to treat your VTE and prevent another one from occurring. Anticoagulants make it harder for blood clots to form, which may help reduce your risk of another VTE.

There are several different types of anticoagulants that can be taken at different times and in different ways (for example, tablets or injections).

You and your doctor may have discussed the different options of anticoagulants. Healthcare teams provide specific guidance for each treatment and, in addition, there is an information leaflet inside the medication pack as a useful reminder.



About ELIQUIS[®] (apixaban)

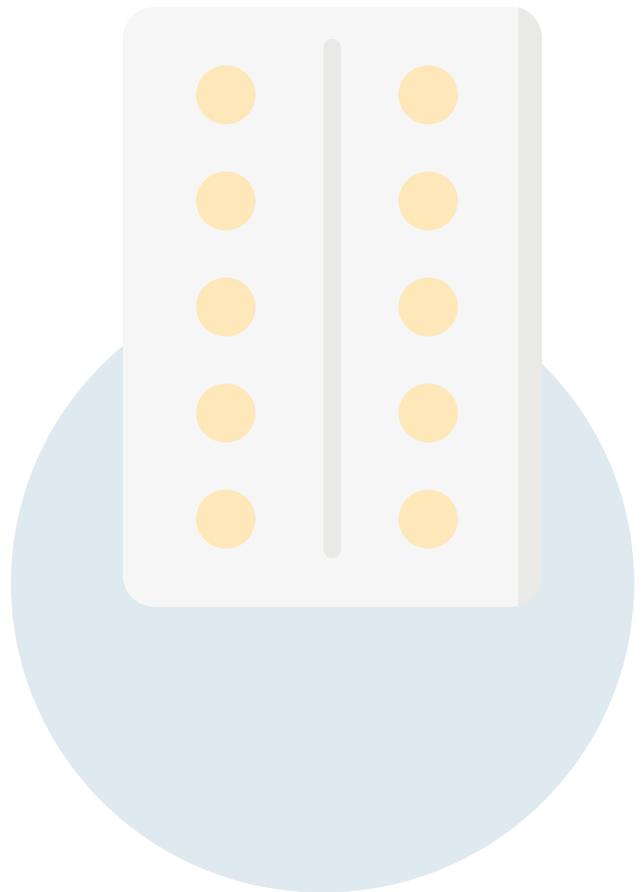


What is ELIQUIS?

ELIQUIS is an anticoagulant that contains the active ingredient apixaban. ELIQUIS works by blocking one of the agents that causes blood clotting (known as Factor Xa).

If your doctor has prescribed ELIQUIS, it is because they believe it is the most suitable medicine for you to treat your DVT or PE and help prevent another one from happening.

Tablets shown are not actual size.



How do I take ELIQUIS®?

You should always take ELIQUIS exactly as your doctor has told you to ensure that ELIQUIS is working for you. Remember your dedicated team of healthcare professionals are available to help you.

ELIQUIS must always be taken twice a day. For example, one in the morning and one in the evening. Try to take the tablets at the same times every day.

To help you remember, try to fit in taking your tablets with a normal routine that happens twice a day, for example, brushing your teeth.

For the first 7 days of treatment, 10mg (two 5mg tablets) ELIQUIS should be taken orally twice daily.

Following the first 7 days, 5mg (one tablet) ELIQUIS should be taken orally twice daily.



Tablets shown are not actual size.



You should also read the Patient Information Leaflet that came inside your pack of ELIQUIS for more information.

You should swallow the ELIQUIS tablet with a glass of water. It can be taken with or without food. If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take ELIQUIS.

How long do I need to take ELIQUIS®?

The length of treatment with ELIQUIS can vary, depending on your treatment plan.

There are two stages of treatment for DVT / PE

Stage 1: The initial treatment stage – this is immediately after your doctor identifies your DVT or PE, and lasts for 3–6 months.

Stage 2: Extended treatment – this is ongoing treatment, after your initial treatment phase ends, and helps to reduce your chance of having another DVT or PE.

Not everyone needs to have extended treatment. Deciding if you should continue taking ELIQUIS is a shared decision that you and your doctor will make together, and they will help guide you through some of the reasons why extended treatment may or may not be right for you.



Do not stop taking ELIQUIS without discussing it with your doctor first!

What should I do if I miss a dose of ELIQUIS®?

If you miss a dose of ELIQUIS, take the medicine as soon as you remember.

Then take the next tablet of ELIQUIS at the usual time and continue with twice-daily intake as before.

If you are not sure what to do, or have missed more than one dose, please remember that you should always call and speak to your doctor, pharmacist or nurse. Please do not hesitate to contact them should you have any concerns.

What should I do if I take too much ELIQUIS?



Tell your doctor immediately if you have taken more than your prescribed dose of ELIQUIS.

Take the medicine pack with you, or have it close by if calling your doctor, even if there are no tablets left. If you take more ELIQUIS than recommended, you may have an increased risk of bleeding.



Things to be aware of when taking ELIQUIS®

- Inform your doctor and dentist that you are taking ELIQUIS if you are having any surgical or dental procedures, including the insertion of a tube (catheter) or an injection into your spinal column to reduce pain – you may need to reduce or temporarily stop taking ELIQUIS before and / or after your treatment as directed by your doctor
- Make sure that you tell your doctor, dentist or pharmacist about any other medicines you are taking, including other prescription medicines, non-prescription medicines (such as aspirin), and supplements
- Certain medicines and supplements can interfere with the anticoagulant effects of ELIQUIS: they may increase the risk of bleeding or make it less effective. Discuss any other medicines or supplements you are taking with your doctor.

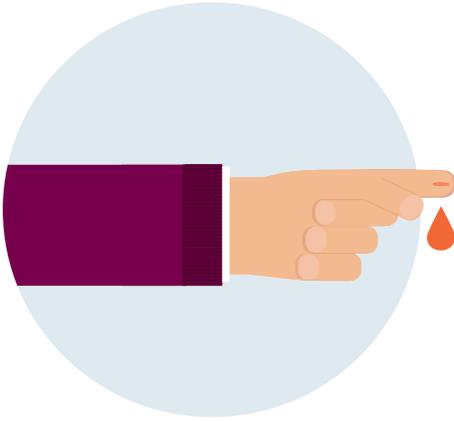
A list of medicines that might affect ELIQUIS can be found in the Patient Information Leaflet inside the medicine package

- As with all anticoagulants, when taking this medicine, it is important that you look out for any signs of bleeding. You should seek medical advice immediately if any signs of bleeding occur and do not seem to stop

You should not take ELIQUIS if:

- you are allergic to any of the ingredients
- you are bleeding excessively
- you have (or are thought to have) a condition that increases the risk of bleeding
- you have liver disease leading to an increased risk of bleeding
- you are taking other medicines to prevent blood clotting

Please speak to your doctor if you have cancer.



In addition, this medicine is not recommended in other instances such as:

- pregnancy
- breast feeding
- in patients with end stage renal disease or who are on dialysis
- in patients with prosthetic heart valves (with and without atrial fibrillation)
- in patients with a condition called antiphospholipid syndrome
- in patients taking certain other medicines (please read the Patient Information Leaflet for the full list)

Please tell your doctor straight away if you think any of these apply to you.

Please ensure that you read the Patient Information Leaflet (inserted in the medicine packaging) thoroughly before taking the medicine.



Important information inside your pack of ELIQUIS® (apixaban)

You will find a Patient Information Leaflet together with a Patient Alert Card inside your pack of ELIQUIS. You should read the Patient Information Leaflet and complete the Patient Alert Card (or ask your doctor to do it or help you with it).

The Patient Alert Card should always be kept with you. You can put it in your wallet, for example.

The Patient Alert Card explains the importance of taking ELIQUIS regularly as instructed by your doctor. It lists the main signs and symptoms of bleeding and lets you know when to seek medical attention.



Possible side effects of ELIQUIS®

Like all medicines, ELIQUIS can cause side effects, although not everybody gets them.

Like other similar medicines (anticoagulants), **this medicine may cause bleeding that can occur in different parts of the body.** Sometimes this can be minor (e.g. your gums bleed more easily when you brush your teeth). Sometimes it can be more serious and may potentially be life-threatening and require immediate medical attention. If you, or those around you, notice any dark brown blood in your urine or vomit, or a black, tarry stool – please seek medical help immediately. Your healthcare team will know what to do.

Side effects may include more bleeding than usual in your:

- nose
- gums
- urine
- stools – as bright red or in the stools
- cough
- vagina



Additional common side effects include:

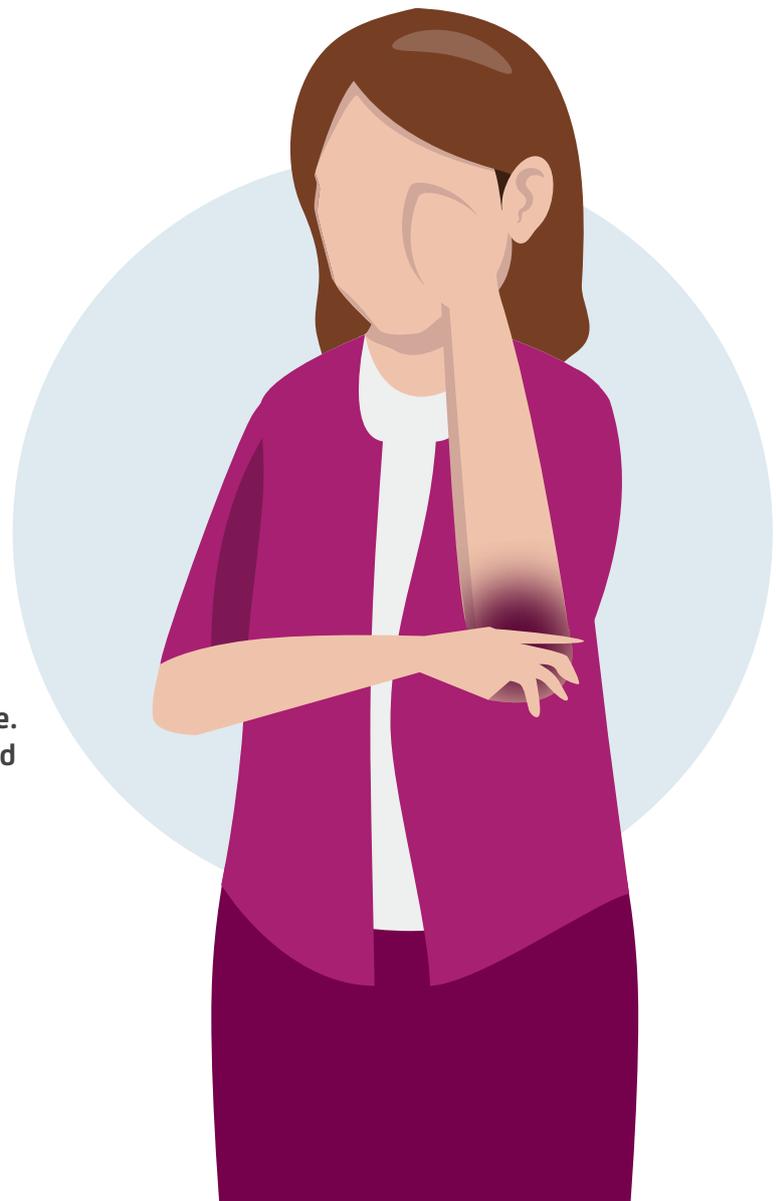
- anaemia, which may cause tiredness or paleness
- nausea (feeling sick)
- blood tests may show an increase in gamma-glutamyltransferase (GGT) or alanine aminotransferase (ALT)

Further information on possible side effects can be found in the Patient Information Leaflet inside your tablet pack.

You can help provide more information on the safety of this medicine by reporting any side effects you may get.

Reporting of side effects: 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 HPRA Pharmacovigilance at www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine. Side effects should also be reported to Bristol-Myers Squibb Medical Information on 1 800 749 749 or medical.information@bms.com

Tell your doctor, nurse, or pharmacist about any side effects you experience, even if they are not listed in the Patient Information Leaflet or in this booklet.



Healthy living after a VTE

Having a VTE can be worrying, but with some small lifestyle changes and with prescribed medication you can help prevent another VTE from occurring. Consider the following lifestyle factors and how they may affect you.



Diet:

Although there are no dietary restrictions with ELIQUIS®, a healthy diet can help with other risk factors that contribute to VTE.

Eating a well-balanced diet in a healthy manner can help you to control your cholesterol levels and maintain a healthy weight. Drinking plenty of water and limiting alcohol can also be beneficial.

Oestrogen:

Women receiving oral contraceptives or hormone replacement therapy should discuss other options with their doctor.



Exercise:

Even if you have VTE, you can still exercise (e.g. walking regularly). Regular physical activity not only helps with weight control, but can also help you to maintain a positive outlook.

Consult your doctor before you start any new forms of exercise, so your doctor can decide if it is suitable for you.

Smoking:

As smoking increases clotting risk, stopping smoking will reduce your risk of having another VTE.

How do I contact my doctor during COVID-19?

Your healthcare team may offer many ways of reaching them in order to minimise person-to-person exposure. This may be by telephone or video consultations, using tools such as Skype or Zoom. They may also offer a texting service to address your queries.

It is important to stay in touch with your healthcare team. Together with your doctor, you should discuss the best way to connect to ensure you can remain in contact, especially during this pandemic.

If you are not familiar with the technology you and your healthcare team have decided to use, ask for help from family, friends, or a carer. They might have some simple and useful tips to share.

Remember that if you are not sure what to do, or have missed more than one dose, your healthcare providers are still there to support you.



It is important you do not cancel or postpone your regular check-ups.

How do I prepare for a remote appointment?

Before your remote appointment



- Think about what you want to get out of your appointment beforehand. This will help you to have more productive conversations, ask specific questions about your condition or care, and cover everything you need
- Take time to prepare and write down key points you want to discuss with your doctor or nurse at your remote consultation. Use specific examples where possible, to provide context
- Some people find it helpful to talk through what they plan to discuss with family, friends, and carers before an appointment
- If you are using a video call tool rather than the phone for your remote appointment, make sure to familiarise yourself with the video software beforehand

You could try it with a friend or family member and make sure everything is working so that your appointment runs smoothly. If you require assistance to set up these tools, ask family, friends, or carers to help.



During your remote appointment



- **Take your time** – try not to feel rushed. Stay relaxed so you remember the key points you wanted to discuss. Referring to your notes should help with this
 - **Be honest** – do not wait to be asked about a symptom or a concern. Tell the doctor or nurse what is on your mind. Give as much information as you can by referring to your list if you have prepared one
 - **Be open** – tell your doctor or nurse about how you are feeling and your overall wellbeing. Try to be specific about what is affecting you
 - **Write things down** – particularly if you do not have time to discuss everything you wanted to raise. If you have someone with you, ask them to write notes for you
 - **Agree on next steps** – discuss and set up a plan of action with your doctor
- 
- **Agree your next appointment date** – find out when your next appointment will be (whether in-person or remote), and what you need to do before then
 - **Ask questions** – do not be afraid to ask questions if there is anything you do not understand. It is important to be completely clear about your treatment
 - **Keep a record** – make sure that you obtain a copy of any relevant documents during your discussion, as you may need to refer to them later



After your remote appointment

Hopefully you will have left your last appointment with a plan of action. Here are some suggestions to help you reflect and remember the key points you discussed and agreed with your doctor:

- **Reflecting on your appointment** – if you took notes during your appointment, it is worth re-reading them now to check if there is anything missing and / or if they make sense. Did you get answers to all your questions?
- **Updating your family, friends or carer** – you might find it useful to tell your family, friends or carer about the outcomes of your appointment. This will ensure that they are fully informed about your treatment and are able to support you with your agreed next steps
- **Follow-up appointments** – while it is still fresh in your mind, it might help to think about what went well and what you would like to do differently at future appointments. What questions would you have liked to ask? Make sure you make a note of these questions so that you have an opportunity to ask them at your next appointment



Please ask your doctor, nurse or pharmacist about anything you are unsure of. Tell your doctor, nurse or pharmacist about any side effects you are experiencing, even if they are not listed in the Patient Information Leaflet or in this booklet.

GETTING SUPPORT

There are a number of Irish organizations which provide invaluable help, information and support to people affected by atrial fibrillation and stroke.

Here is the contact details of one organization which you may find useful:

Thrombosis Ireland

Unit 4 Terenure Enterprise Centre,
17 Rathfarnham Road, Dublin 6W, D6W YW11

Telephone: +353 87 3634828

Website: www.thrombosis.ie

Email: info@thrombosisireland.ie

Questions to consider asking your doctor



01. I am worried about obtaining further supplies of my medication – what should I do?

01

02. Does it matter that I am taking other medications?

02

03. Can I still exercise? If yes, which exercises are suitable for me?

03

04. If I think I am developing coronavirus symptoms – what should I do?

04

05. Will I have to have a consultation in person?

05

06. What if I have more questions – who should I ask?

06

07. I am feeling isolated – are other sources of support or advice available to me?

07

