

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Eliquis.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Eliquis against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Eliquis is used for

What Eliquis does

This medicine is used to:

- prevent blood clots in your veins after a hip or knee replacement surgery. After an operation you are at an increased risk of getting blood clots.
- treat blood clots occurring in deep veins (Deep Vein Thrombosis [DVT]) and clots in your lungs (Pulmonary Embolism [PE]) and also to prevent these from recurring.
- prevent stroke and blood clots in a condition called atrial fibrillation, which is a type of abnormal heart rhythm. With atrial fibrillation, part of the heart does not beat the way it should. This can lead to blood clots forming and increase your risk of having a stroke.

How Eliquis works

The active substance in Eliquis is apixaban. It belongs to a group of medicines called antithrombotic agents.

It works by inhibiting a blood clot forming substance called Factor Xa.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Use in Children

There is not enough information to recommend the use of this medicine in children and adolescents under the age of 18 years.

Before you take Eliquis

When you must not take it

Do not take Eliquis if you have an allergy to:

- any medicine containing apixaban
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing

- swelling of the face, lips, tongue or other parts of the body

- rash, itching or hives on the skin

Do not take Eliquis if you have, or have had, any of the following medical conditions:

- any disease or injury to a body organ that is actively bleeding or at high risk of bleeding e.g. bleeding ulcer in the stomach or bowel, recent bleeding in the brain, cancer at high risk of bleeding
- liver disease which leads to an increased risk of bleeding
- severely reduced kidney function. Your doctor will determine your kidney function
- a recent operation on the brain, spinal column or eye(s)
- recent brain or spine injury
- abnormalities of any blood vessels that may lead to an increase in bleeding
- any blood vessel abnormalities of your oesophagus or "gullet"
- any disease or injury to a body organ that could lead to significant bleeding e.g. stomach ulcers, bowel ulcers.

Do not take Eliquis if you are taking the following medicines:

- medicines for fungal infections e.g. ketoconazole, itraconazole, voriconazole or posaconazole, unless they are only applied to the skin
- anti-viral medicines for HIV/AIDS e.g. ritonavir
- other medicines to stop your blood from clotting e.g. heparin, enoxaparin, warfarin, rivaroxaban or dabigatran.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are 75 years or older or if you have or have had any of the following medical conditions which may lead to an increased risk of bleeding:

- a heart condition known as bacterial endocarditis
- type of stroke called "haemorrhagic stroke"
- blood disorders that affect your ability to form clots and stop bleeding
- recent or past ulcer of your stomach or bowel
- moderate or mild kidney disease
- liver disease
- have a lung condition called bronchiectasis
- have had a history of bleeding in your lungs
- high blood pressure that is not controlled with medications.

Your doctor may decide to keep you under closer observation.

Tell your doctor if you have a prosthetic heart valve or severe rheumatic heart disease, especially mitral stenosis (problem with the mitral valve in your heart).

If you are having hip or knee replacement surgery and your operation involves a catheter or injection into your spinal column e.g. for epidural or spinal anaesthesia or pain reduction:

- tell your doctor immediately if you get numbness or weakness of your legs or problems with your bowel or bladder after the end of anaesthesia, because urgent care is necessary.

Tell your doctor if you are pregnant or plan to become pregnant.

Eliquis is not recommended for use in pregnant women. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breast-feeding or intend to breast-feed.

Eliquis is not recommended during breast-feeding. You should not breast-feed and take Eliquis at the same time. The active ingredient in Eliquis may be present in breast milk and poses a bleeding risk to the baby. You and your doctor should decide if you will take Eliquis or breast-feed.

If you have not told your doctor about any of the above, tell him/her before you start taking Eliquis.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may be affected by Eliquis or may affect how it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Tell your doctor or pharmacist if you are taking any of the following:

- medicines used to treat fungal infections such as ketoconazole (Nizoral®), itraconazole (Sporanox®), voriconazole (Vfend®) and posaconazole (Noxafil®)
- anti-viral medicines for HIV/AIDS e.g. ritonavir (Norvir®)
- rifampin or rifampicin (Rifadin®)
- medicines to treat epilepsy such as phenytoin (Dilantin®), carbamazepine (Tegretol®), phenobarbitone
- St John's wort
- medicines to treat depression such as sertraline, citalopram and venlafaxine
- medicines used to treat pain and inflammation including non-steroidal anti-inflammatory drugs (NSAIDs) such as naproxen (Naprosyn®) or aspirin (Aspro®)
- other medicines used to prevent blood clots such as enoxaparin (Clexane®), clopidogrel (Iscover®, Plavix®),

heparin, fondaparinux (Arixtra®), bivalirudin (Angiomax®), rivaroxaban (Xarelto®), dabigatran (Pradaxa®), dipyridamole (Persantin®)

- quinidine
- verapamil
- diltiazem
- amiodarone
- the antibiotic, clarithromycin.

(Not all brand names are given above so check with your doctor or pharmacist).

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Eliquis

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many tablets you need to take each day.

If you are having hip or knee replacement surgery

The recommended dose is one 2.5 mg tablet taken twice a day.

If you have blood clots

The recommended dose to treat blood clots is two 5 mg tablets taken twice a day for 7 days, then one 5 mg tablet taken twice a day.

The recommended dose to prevent blood clots that recur is one 2.5 mg tablet taken twice daily.

If you have atrial fibrillation

The recommended dose is normally one 5 mg tablet taken twice a day.

The recommended dose is one 2.5 mg tablet taken twice a day if you meet any two of the following:

- are 80 years or older
- weigh 60 kilograms or under
- have reduced kidney function.

How to take it

Swallow the tablet(s) whole with a full glass of water.

If you are unable to swallow the tablet(s) whole, follow the steps below to crush the tablet(s). This will help make sure that all of the crushed tablet(s) will be taken.

- **use a mortar and pestle or a similar device to crush the tablet(s)**
- **transfer the powder to a drinking glass or a small bowl**
- **when using water, 5% dextrose in water or apple juice:**
 - **add a small amount of water/5% dextrose in water/apple juice (30 mL) to the mortar and pestle/device and stir**
 - **transfer the water/5% dextrose in water/apple juice to the drinking glass**
 - **mix the powder with the water/5% dextrose in water/apple juice and drink right away**
 - **rinse the glass with a small amount of water/5% dextrose in water/apple juice and drink right away.**

- **when using apple sauce:**
 - **mix the powder with a small amount of apple sauce (30 g) in a small bowl and eat with a spoon right away**
 - **add a small amount of water (30 mL) to the mortar and pestle/device and stir**
 - **transfer the water to the bowl and drink right away**
 - **rinse the bowl and the spoon with a small amount of water and drink right away.**

If necessary, your doctor may also give you the crushed tablet(s) mixed in 60 mL of water or 5% dextrose in water, through a nasogastric tube.

It does not matter if you take this medicine before or after food.

When to take it

Take the first tablet as directed by your doctor.

If you are having hip or knee replacement surgery it is usual to start taking your tablets 12 to 24 hours after your operation.

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, you may be at an increased risk of developing a blood clot, which can lead to serious problems such as a stroke if you have atrial fibrillation.

If you are having hip or knee replacement surgery

If you have had a hip replacement, you will usually take the tablets for about 5 weeks.

If you have had a knee replacement, you will usually take the tablets for about 2 weeks.

If you have blood clots

To treat blood clots you will usually take the tablets for up to 6 months. If necessary, you may need to continue taking the tablets, usually at a lower dose, to prevent further blood clots.

If you have atrial fibrillation

Continue taking your medicine for as long as your doctor tells you.

If you require cardioversion

If your abnormal heartbeat needs to be restored by a procedure called cardioversion, take your medicine at the times your doctor tells you, to help prevent blood clots that may result in strokes or other problems.

If you forget to take it

Take your next tablet as soon as you remember, then continue taking the tablets as normal (twice a day).

Do not take a double dose to make up for the forgotten tablet.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre on 13 11 26 for advice, or go to the Accident and Emergency Department at the nearest hospital, if you think that you or anyone else may have taken too much Eliquis.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include bleeding that does not stop.

While you are taking Eliquis

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Eliquis.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have any surgery or procedure, including dental surgery, tell your surgeon, doctor or dentist that you are taking this medicine.

Eliquis should be temporarily stopped before surgery.

Your doctor will tell you when to stop using Eliquis before your surgery or procedure.

Your doctor will also tell you when you can start taking Eliquis after your surgery.

Tell your doctor that you are taking Eliquis if your doctor is planning for you to have an anaesthetic injection in your back (spinal or epidural injection).

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take Eliquis to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without first checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have serious side effects.

Things to be careful of

Eliquis contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking it.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Eliquis.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

It can be difficult to tell whether side effects are the result of taking Eliquis, effects of

your condition or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

Do not be alarmed by the list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if...

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- tiredness, weakness, paleness, dizziness, light-headedness, headache - which can be due to low iron in the blood
- bleeding from any part of your body, no matter how minor, as these may be difficult to control
- bruising
- nausea (feeling sick), vomiting
- diarrhoea or constipation
- fever
- sore nasal passages and throat
- frequent need to urinate or pain while urinating
- coughing.

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if...

Tell your doctor as soon as possible if you notice any of the following:

- excessive bleeding or prolonged bleeding. There is no antidote to reverse this bleeding. It is important to contact your doctor immediately if you experience excessive or prolonged bleeding.
- stomach swelling, yellowing of the skin or whites of the eyes (due to liver problems)
- oozing from your surgical wound
- swelling of the hands, ankles or feet due to water retention.

The above list includes serious side effects that may require medical attention.

Go to hospital if...

Tell your doctor immediately or go to the Accident and Emergency Department at your nearest hospital, if you notice any of the following:

- bleeding from your nose
- if you have dark brown urine or blood in your urine
- if you cough up blood
- if you vomit and it is black
- if you have black stools or blood in your stools
- excessive bleeding or prolonged bleeding. There is no antidote to reverse this bleeding. It is important to contact your doctor immediately if you experience excessive or prolonged bleeding.
- if you have an allergic reaction to Eliquis. Symptoms may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of the other possible side effects (for example, changes in liver function) can only be found when your doctor does tests from time to time to check your progress.

After taking Eliquis

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store Eliquis or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Eliquis 2.5 mg tablets are yellow and round with "893" on one side and "2 1/2" on the other.

They are packed in blister packs in cartons of 10, 14, 20, 30, 60 or 100 tablets.

Eliquis 5 mg tablets are pink and oval-shaped with "894" on one side and "5" on the other.

They are packed in blister packs in cartons of 14, 20, 28, 56, 60, 100, 112, 120 and 168 tablets.

Not all pack sizes may be available.

Ingredients

Eliquis tablets contain 2.5 mg or 5 mg of apixaban as the active ingredient.

They also contain:

- lactose
- lactose monohydrate
- microcrystalline cellulose
- croscarmellose sodium
- sodium lauryl sulfate
- magnesium stearate
- hypromellose
- titanium dioxide
- glycerol triacetate
- yellow iron oxide (2.5 mg tablets)
- red iron oxide (5 mg tablets)

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Sponsored and Supplied by:

Bristol-Myers Squibb Australia Pty Ltd
4 Nexus Court
Mulgrave VIC 3170

Toll free number: 1800 067 567
MedInfo.Australia@bms.com

Also distributed by:

Pfizer Australia Pty Ltd
Level 17, 151 Clarence Street
Sydney NSW 2000
Australia

Toll Free Number: 1800 675 229
medicalaffairs.anz@pfizer.com

Australian registration numbers

2.5 mg tablet: AUST R 172244

5 mg tablet: AUST R 193474

Date of preparation

This leaflet was prepared in December 2018.

® ELIQUIS is a registered trademark of Bristol-Myers Squibb Company.

© Copyright of Bristol-Myers Squibb Company 2018.