

XAGULANT FILM COATED TABLETS

Apixaban (2.5 mg, 5mg)

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What Xagulant is used for

Xagulant is used to:

- prevent blood clots in veins (venous thromboembolic events [VTE]) after hip or knee replacement surgery.
- prevent stroke and blood clots in adult patients with a condition called non-valvular atrial fibrillation (NVAf), which is a type of irregular heart rhythm with one or more risk factors, such as:
 - previous stroke condition or mini stroke (transient ischaemic attack [TIA])
 - age ≥ 75 years
 - high blood pressure (hypertension)
 - high blood sugar levels (diabetes mellitus)
 - symptomatic heart failure (NYHA Class \geq II)
- 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.

How Xagulant works

Xagulant contains apixaban which inhibit factor Xa (an important component of blood clotting) and this prevents blood clot formation.

Before you use Xagulant

- When you must not use it

Do not take Xagulant if:

- hypersensitivity to apixaban or any other ingredients of this medicine (listed in Product Description)
- an injury to a body organ or any internal bleeding
- liver disease associated with a bleeding disorder called

coagulopathy and an increased risk of bleeding

- any condition or injury to a body organ that could lead to significant bleeding (such as ulcers in stomach; cancerous growth; recent brain or spinal injury; recent brain, spinal or eye surgery; bleeding in the brain; abnormal, enlarged veins in the tube that connects the throat and stomach (esophagus); an abnormal connection between arteries and veins, a bulging, dilation or ballooning in the wall of a blood vessel; abnormalities within brain or spine)
- you are taking medicines to prevent blood clotting like heparins, heparin derivatives, warfarin, rivaroxaban and dabigatran
- severe kidney disease or kidney failure or if you are undergoing treatment (dialysis).

Xagulant should not be used in children and adolescent under the age of 18 as the safety and efficacy have not been established.

-Before you start to use it

Tell your doctor or pharmacist if you are/have:

- any condition with increased risk of bleeding that affect your ability to form clots
- atrial fibrillation along with other conditions that requires mono or dual antiplatelet therapy
- undergoing procedures such as spinal/epidural anaesthesia or puncture and treated with antithrombotic agents to prevent clot
- a prosthetic heart valve
- the need to have surgery or a procedure which may cause bleeding
- cancer
- any kidney or liver disease
- an elderly body weight less than 60 kg
- having hip fracture surgery
- to undergo any clotting tests
- antiphospholipid syndrome (a disorder of the immune system

that causes an increased risk of blood clots)

- hereditary problems of galactose intolerance
- taking acetylsalicylic acid (ASA) as it increases the risk for bleeding in patients treated with Xagulant.

Pregnancy and lactation

Xagulant is not recommended during pregnancy. There are no data from the use of Xagulant in pregnant women.

It is unknown whether Xagulant or its byproducts are excreted in human milk. A risk to newborns and infants cannot be excluded. Please consult your doctor for advice if you should stop breast-feeding or to stop/not start Xagulant.

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with

Xagulant, for example:

- antifungal (e.g. ketoconazole, itraconazole, voriconazole and posaconazole, fluconazole)
- antiviral for HIV/AIDS (e.g. ritonavir)
- antibiotics (e.g. rifampicin, clarithromycin)
- medicine for epilepsy (e.g. phenytoin, carbamazepine, phenobarbital)
- St John's wort (herbal supplement used for depression)
- medicine for high blood pressure or heart problem (e.g. amiodarone, diltiazem, verapamil, atenolol, digoxin, quinidine)
- antidepressants called selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs)

- painkillers including non-steroidal anti-inflammatory drugs (NSAIDs) (e.g. naproxen, acetylsalicylic acid)
- medicines to prevent blood clots (e.g. enoxaparin, clopidogrel, prasugrel, dipyridamole, dextran, sulfipyrazone)
- gastric medicine (e.g. famotidine)
- activated charcoal

How to use Xagulant

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Prevention of blood clots in veins (venous thromboembolic events [VTE]) after hip or knee replacement surgery:

The recommended dose is one tablet of Xagulant 2.5mg taken orally twice daily. The initial dose should be taken 12 to 24 hours after surgery.

In patients undergoing hip replacement surgery, the recommended duration of treatment is 32 to 38 days.

In patients undergoing knee replacement surgery, the recommended duration of treatment is 10 to 14 days.

Prevention of stroke and blood clots in adults with irregular heart rhythm (non-valvular atrial fibrillation [NVAF]):

The recommended dose is one tablet of Xagulant 5mg taken orally twice daily.

The recommended dose reduction is one tablet of Xagulant 2.5mg taken orally twice daily in individuals with at least two of the following characteristics:

- age \geq 80 years
- body weight \leq 60 kg
- serum creatinine \geq 1.5 mg/dL (133 micromole/L).

Therapy should be continued long-term.

Treatment of blood clots occurring in deep veins (Deep Vein Thrombosis

[DVT] and clots in your lungs (Pulmonary Embolism [PE]):

The recommended dose for the treatment of acute DVT and treatment of PE is two tablets of Xagulant 5mg taken orally twice daily for the first 7 days followed by one tablet of Xagulant 5mg taken orally twice daily.

The recommended short duration of treatment (at least 3 months) should be based on transient risk factors (e.g. recent surgery, trauma, immobilization)

Prevention of recurrent blood clots occurring in deep veins (Deep Vein Thrombosis [DVT] and clots in your lungs (Pulmonary Embolism [PE]): The recommended dose is one tablet of Xagulant 2.5mg taken orally twice daily following the completion of 6 months of treatment for DVT or PE with Xagulant 5mg twice daily or with another anticoagulant.

- When to use it

Use as directed by your doctor or pharmacist. Xagulant tablets should be swallowed with water, with or without food.

If you are unable to swallow whole tablets, Xagulant tablets may be crushed and suspended in water, or 5% dextrose in water (D5W), or apple juice or mixed with apple puree and immediately administered orally. Alternatively, Xagulant tablets may be crushed and suspended in 60 mL of water or D5W and immediately delivered through a nasogastric tube.

Crushed Xagulant tablets are stable in water, D5W, apple juice, and apple puree for up to 4 hours.

- How long to use it

Continue using Xagulant for the duration that the doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it. Take the missed dose as soon as you remember and then continue with twice

daily intake as before. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause a higher risk of bleeding.

While you are using it

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Xagulant.

Tell your doctor immediately if you become pregnant while using this medication.

Take Xagulant only with a doctor's prescription.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give Xagulant to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Xagulant tablets has no or negligible influence on the ability to drive and use machines.

If the tablets make you feel sick, dizzy or tired, or give you a headache, do not

drive or use machines and contact your doctor immediately.

Side Effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

The following side effects are common if you take Xagulant to prevent blood clots in veins after a hip or knee replacement surgery:

- a deficiency of red blood cells or haemoglobin in the blood (anaemia)
- profuse bleeding from a ruptured blood vessel (haemorrhage),
- a localized bleeding outside of blood vessels (haematoma)
- nausea
- bruising and swelling

If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

The following side effects are common if you take Xagulant to prevent stroke or a blood clot from forming in the heart in patients with an irregular heart beat and at least one additional risk factor:

- a deficiency of red blood cells or haemoglobin in the blood (anaemia)
- bleeding in your eyes, stomach, gums, nose or rectum
- profuse bleeding from a ruptured blood vessel (haemorrhage), a localized bleeding outside of blood vessels (haematoma)
- low blood pressure (hypotension)
- nausea
- an increase in gamma-glutamyltransferase (an enzyme present in body)
- blood in urine
- bruising

The following side effects are common if you take Xagulant to treat blood clots occurring in deep veins and clots in your lungs and also to

prevent their recurrence:

- a deficiency of red blood cells or haemoglobin in the blood (anaemia)
- low platelet level in blood (thrombocytopenia)
- profuse bleeding from a ruptured blood vessel (haemorrhage),
- a localized bleeding outside of blood vessels (haematoma)
- bleeding in your nose, stomach, mouth, gums or rectum
- abnormal bleeding from urinary tract, vagina or other reproductive organs
- nausea
- an increase in gamma-glutamyltransferase and alanine aminotransferase (enzymes present in body)
- skin rash
- blood in urine
- bruising and swelling

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Xagulant

- Storage

Keep out of the reach and sight of children.

Do not store above 30°C. Store in the original container.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Xagulant 2.5mg Film Coated Tablets are brown, film-coated, round, biconvex, beveled edge tablet debossed with X2 on one side of the tablet and M on other side.

Xagulant 5mg Film Coated Tablets are brown, film-coated, oval, biconvex, beveled edge tablet debossed with X5 on one side of the tablet and M on other side.

- Ingredients

- Active ingredient

Each Xagulant 2.5mg Film Coated Tablet contains 2.5mg apixaban
Each Xagulant 5mg Film Coated Tablet contains 5mg apixaban

- Inactive ingredients

Tablet core: lactose anhydrous, microcrystalline cellulose, croscarmellose sodium, sodium lauryl sulfate, magnesium stearate
Film coat: hypromellose, polyethylene glycol, sodium lauryl sulfate, titanium dioxide, red iron oxide, yellow iron oxide

- MAL number(s):

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MAL25116020ARZ

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Product Registration Holder

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