

Package leaflet: Information for the user
Xarelto® 10 mg film-coated tablets
(rivaroxaban)

Your medicine is known as the above but will be referred to as Xarelto throughout the remainder of this leaflet.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Xarelto is and what it is used for
2. What you need to know before you take Xarelto
3. How to take Xarelto
4. Possible side effects
5. How to store Xarelto
6. Contents of the pack and other information

1. What Xarelto is and what it is used for

Xarelto contains the active substance rivaroxaban and is used in adults to

- prevent blood clots in the veins after a hip or knee replacement operation. Your doctor has prescribed this medicine for you because after an operation you are at an increased risk of getting blood clots.
- treat blood clots in the veins of your legs (deep vein thrombosis) and in the blood vessels of your lungs (pulmonary embolism), and to prevent blood clots from re-occurring in the blood vessels of your legs and/or lungs.

Xarelto belongs to a group of medicines called antithrombotic agents. It works by blocking a blood clotting factor (factor Xa) and thus reducing the tendency of the blood to form clots.

2. What you need to know before you take Xarelto

Do not take Xarelto

- if you are allergic to rivaroxaban or any of the other ingredients of this medicine (listed in section 6)
- if you are bleeding excessively
- if you have a disease or condition in an organ of the body that increases the risk of serious bleeding (e.g. stomach ulcer, injury or bleeding in the brain, recent surgery of the brain or eyes)
- if you are taking medicines to prevent blood clotting (e.g. warfarin, dabigatran, apixaban or heparin), except when changing anticoagulant treatment or while getting heparin through a venous or arterial line to keep it open
- if you have a liver disease which leads to an increased risk of bleeding
- if you are pregnant or breast-feeding

Do not take Xarelto and tell your doctor if any of these apply to you.

Warnings and precautions

Talk to your doctor or pharmacist before taking Xarelto.

Take special care with Xarelto

- if you have an increased risk of bleeding, as could be the case in situations such as:
 - moderate or severe kidney disease, since your kidney function may affect the amount of medicine that works in your body
 - if you are taking other medicines to prevent blood clotting (e.g. warfarin, dabigatran, apixaban or heparin), when changing anticoagulant treatment or while getting heparin through a venous or arterial line to keep it open (see section "Other medicines and Xarelto")
 - bleeding disorders
 - very high blood pressure, not controlled by medical treatment
 - diseases of your stomach or bowel that might result in bleeding, e.g. inflammation of the bowels or stomach, or inflammation of the oesophagus (gullet), e.g. due to gastroesophageal reflux disease (disease where stomach acid goes upwards into the oesophagus) or tumours located in the stomach or bowels or genital tract or urinary tract
 - a problem with the blood vessels in the back of your eyes (retinopathy)
 - a lung disease where your bronchi are widened and filled with pus (bronchiectasis), or previous bleeding from your lung
- if you have a prosthetic heart valve
- if you know that you have a disease called antiphospholipid syndrome (a disorder of the immune system that causes an increased risk of blood clots), tell your doctor who will decide if the treatment may need to be changed.
- if your doctor determines that your blood pressure is unstable or another treatment or surgical procedure to remove the blood clot from your lungs is planned.

If any of the above apply to you, tell your doctor before you take Xarelto. Your doctor will decide, if you should be treated with this medicine and if you should be kept under closer observation.

If you need to have an operation

- it is very important to take Xarelto before and after the operation exactly at the times you have been told by your doctor.
- If your operation involves a catheter or injection into your spinal column (e.g. for epidural or spinal anaesthesia or pain reduction):
 - it is very important to take Xarelto exactly at the times you have been told by your doctor
 - 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.

Children and adolescents

Xarelto 10 mg tablets are **not recommended for people under 18 years of age**. There is not enough information on their use in children and adolescents.

Other medicines and Xarelto

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

■ **If you are taking**

- some medicines for fungal infections (e.g. fluconazole, itraconazole, voriconazole, posaconazole), unless they are only applied to the skin
- ketoconazole tablets (used to treat Cushing's syndrome - when the body produces an excess of cortisol)
- some medicines for bacterial infections (e.g. clarithromycin, erythromycin)
- some anti-viral medicines for HIV / AIDS (e.g. ritonavir)
- other medicines to reduce blood clotting (e.g. enoxaparin, clopidogrel or vitamin K antagonists such as warfarin and acenocoumarol)
- anti-inflammatory and pain relieving medicines (e.g. naproxen or acetylsalicylic acid)
- dronedarone, a medicine to treat abnormal heart beat
- some medicines to treat depression (selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs))

If any of the above apply to you, tell your doctor before taking Xarelto, because the effect of Xarelto may be increased. Your doctor will decide, if you should be treated with this medicine and if you should be kept under closer observation.

If your doctor thinks that you are at increased risk of developing stomach or bowel ulcers, he may also use a preventative ulcer treatment.

■ **If you are taking**

- some medicines for treatment of epilepsy (phenytoin, carbamazepine, phenobarbital)
- St John's Wort (*Hypericum perforatum*), a herbal product used for depression
- rifampicin, an antibiotic

If any of the above apply to you, tell your doctor before taking Xarelto, because the effect of Xarelto may be reduced. Your doctor will decide, if you should be treated with Xarelto and if you should be kept under closer observation.

Pregnancy and breast-feeding

Do not take Xarelto if you are pregnant or breast-feeding. If there is a chance that you could become pregnant, use a reliable contraceptive while you are taking Xarelto. If you become pregnant while you are taking this medicine, tell your doctor immediately, who will decide how you should be treated.

Driving and using machines

Xarelto may cause dizziness (common side effect) or fainting (uncommon side effect) (see section 4 "Possible side effects"). You should not drive, ride a bicycle or use any tools or machines if you are affected by these symptoms.

Xarelto contains lactose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. How to take Xarelto

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much to take

- To prevent blood clots in the veins after a hip or knee replacement operation
The recommended dose is one tablet Xarelto 10 mg once a day.
- To treat blood clots in the veins of your legs and blood clots in the blood vessels of your lungs, and for preventing blood clots from re-occurring
After at least 6 months blood clot treatment, the recommended dose is either one 10 mg tablet once a day or one 20 mg tablet once a day. Your doctor has prescribed you Xarelto 10 mg once a day.

Swallow the tablet preferably with water.
Xarelto can be taken with or without food.

If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take Xarelto. The tablet may be crushed and mixed with water or apple puree immediately before you take it. If necessary, your doctor may also give you the crushed Xarelto tablet through a stomach tube.

When to take Xarelto

Take the tablet every day until your doctor tells you to stop. Try to take the tablet at the same time every day to help you to remember it.

Your doctor will decide how long you must continue treatment.

To prevent blood clots in the veins after a hip or knee replacement operation:

Take the first tablet 6 - 10 hours after your operation.

If you have had a major hip operation you will usually take the tablets for 5 weeks.

If you have had a major knee operation you will usually take the tablets for 2 weeks.

If you take more Xarelto than you should

Contact your doctor immediately if you have taken too many Xarelto tablets. Taking too much Xarelto increases the risk of bleeding.