

PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before you start taking Xarelto 10.

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

Xarelto 10 has been prescribed for you personally and you should not share it with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS: S4

PROPRIETARY NAME AND DOSAGE FORM:

XARELTO 10 Film-coated tablets

WHAT XARELTO 10 CONTAINS:

The active substance is rivaroxaban. Each tablet contains 10 mg of rivaroxaban. Contains lactose.

The other ingredients are:

Tablet core: Cellulose microcrystalline, Croscarmellose sodium, Hydroxypropylmethylcellulose 2910, Lactose monohydrate, Sodium laurylsulfate, Magnesium stearate.

Film coat: Polyethylene glycol, Hydroxypropylmethylcellulose 2910, Titanium dioxide (E171), Ferric oxide red (E172).

WHAT XARELTO 10 IS AND WHAT IT IS USED FOR:

Xarelto 10 is used to prevent blood clots in your veins after a major operation on your legs. For example this could be an operation on your hip or knee. Your doctor has prescribed Xarelto 10 for you because after an operation you are at an increased risk of getting blood clots.

The active substance is rivaroxaban. It belongs to a group of medicines called antithrombotic agents. It works by inhibiting blood clotting Factor Xa.

BEFORE YOU USE XARELTO 10:

Do not take Xarelto 10 and tell your doctor if any of the following apply to you:

- **if you are allergic** (hypersensitive) to rivaroxaban or any of the other ingredients of Xarelto 10
- **if you are bleeding excessively**
- **if you have severe liver disease** which leads to an increased risk of bleeding
- **if you are pregnant or breast feeding**

Take special care with Xarelto 10:

- if you have **severe kidney disease**
- if you have **an increased risk of bleeding** such as:
 - **bleeding disorders**
 - **very high blood pressure**, not controlled by medical treatment
 - **active ulcer or a recent ulcer** of your stomach or bowel
 - **a problem with the blood vessels in the back of your eyes** (retinopathy)
 - **recent bleeding in your brain** (intracranial or intracerebral bleeding)
 - **a recent operation on your brain, spinal column or eye**

Tell your doctor before you take Xarelto 10, if any of these apply to you. Your doctor may decide to keep you under closer observation.

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 10 before and after the injection or removal of the catheter 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.

Taking other medicines with Xarelto 10:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of Xarelto 10 with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

If you are taking:

- some **medicines for fungal infections** (e.g. ketoconazole), unless they are only applied to the skin
- **anti-viral medicines for HIV / AIDS** (e.g. ritonavir)
- other medicines to **reduce blood clotting** (e.g. enoxaparin or clopidogrel)
- **anti-inflammatory and pain relieving medicines** (e.g. naproxen or acetylsalicylic acid)

Tell your doctor before taking Xarelto 10, because its effect may be increased. Your doctor may decide to keep you under closer observation.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby while taking Xarelto 10, please consult your doctor, pharmacist or other healthcare professional for advice.

If you are pregnant or breastfeeding don't take Xarelto 10. If there is a chance that you could become pregnant, use a reliable contraceptive while you are taking Xarelto 10. If you become pregnant while you are taking Xarelto 10, immediately tell your doctor who will decide how you should be treated.

HOW TO USE XARELTO 10:

Do not share medicines prescribed for you with others.

Always take Xarelto 10 exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How much to take:

The usual dose is one Xarelto 10 tablet (10 mg) once a day.

Swallow the tablet preferably with water.

Xarelto 10 tablet can be taken with or without food.

When to take Xarelto 10:

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

Then take a 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.

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.

Children and adolescents up to 18 years of age:

Don't give Xarelto 10 tablets to people under 18 years of age. There is not enough information on its use in children and adolescents.

If you take more Xarelto 10 than you should:

Contact your doctor immediately if you have taken too many Xarelto 10 tablets. Taking too much Xarelto 10 increases the risk of bleeding.

Please consult your doctor or pharmacist in the case of accidental overdose. If neither is available, rush the patient to the nearest hospital or poison control centre.

If you forget to take Xarelto 10:

If you have missed a dose, take it as soon as you remember. Take the next tablet on the following day and then carry on taking a tablet once a day as normal.

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

If you stop taking Xarelto 10:

Don't stop taking Xarelto 10 without talking to your doctor first, because Xarelto 10 prevents the development of a serious condition.

If you have any further questions on the use of Xarelto 10, ask your doctor or pharmacist.

POSSIBLE SIDE-EFFECTS:

Not all side-effects reported for Xarelto 10 are included in this leaflet. Should your general health worsen while taking Xarelto 10, please consult your doctor, pharmacist or other healthcare professional for advice.

Xarelto 10 can cause side-effects, although not everybody gets them.

Like other similar medicines (antithrombotic agents), Xarelto 10 may cause bleedings. In some cases these bleedings may not be obvious.

Tell your doctor, if you experience any of the following side-effects:

- **long or excessive bleeding**
- **exceptional weakness, tiredness, paleness, dizziness, headache or unexplained swelling.**

Your doctor may decide to keep you under closer observation or change how you should be treated.

The following side-effects have been reported for Xarelto 10:

Common side-effects

(may affect up to 1 in 10 people)

- bleeding following your operation
- anaemia (reduction in the quantity of oxygen-carrying material (haemoglobin) in the blood)
- feeling sick (nausea)
- blood tests may show an increase in some liver enzymes

Uncommon side-effects

(may affect up to 1 in 100 people)

- bleeding in your stomach or bowel, genital bleeding, nose bleed
- haematoma (an accumulation of blood within the tissue that clots to form a solid swelling), bruising
- blood in your urine
- oozing from surgical wound
- raised heart beat (tachycardia)
- low blood pressure
- feeling unwell (weakness, tiredness), headache, dizziness, fainting
- stomach ache, indigestion (constipation, diarrhoea, dyspepsia (gastric indigestion), vomiting)
- dry mouth
- localised swelling, swelling in your limbs (oedema)
- fever
- pain in your limbs
- rash, itchy skin, hives
- impaired function of your kidneys

- blood tests may show an increase in bilirubin, some pancreatic enzymes or in the number of platelets (thrombocytosis)

Rare side-effects

(may affect up to 1 in 1000 people)

- impaired function of your liver
- allergic skin reactions

In addition the following side-effects have been reported for Xarelto 10: adrenal bleeding, bleeding from the whites of your eyes or bleeding from a stomach ulcer leading to death, yellowing of the skin and eye (jaundice), hypersensitivity and coughing blood.

IDENTIFICATION OF XARELTO 10:

Xarelto 10 film-coated tablets are light red, round, biconvex tablets, 6 mm in diameter, debossed with "Triangle 10" on the top side and the BAYER-cross on the bottom side of the tablet.

PRESENTATION OF XARELTO 10:

Xarelto 10 film-coated tablets are packed in colourless, transparent PP (polypropylene)/aluminium blister strips or colourless, transparent PVC/PVDC/aluminium blister strips containing 5 or 10 tablets per blister. Pack sizes: 5 tablets (1 x 5's blister), 10 tablets (1 x 10's blister), 30 tablets (3 x 10's blister) or 100 tablets (10 x 10's blister).

STORING AND DISPOSING OF XARELTO 10:

Store below 30 °C. Keep blister strips in the original carton until use.

Do not use Xarelto 10 after the expiry date which is stated on the carton and on each blister.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

REGISTRATION NUMBER:

42/8.2/1046

NAME AND BUSSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Bayer (Pty) Ltd

Reg. No.: 1968/011192/07

27 Wrench Road

ISANDO

1609

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

27 January 2010.