

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Xarelto 10 mg film-coated tablets Rivaroxaban

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Xarelto is and what it is used for
2. Before you take Xarelto
3. How to take Xarelto
4. Possible side effects
5. How to store Xarelto
6. Further information

1. WHAT XARELTO IS AND WHAT IT IS USED FOR

Xarelto is used to prevent blood clots in your 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.

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. BEFORE YOU TAKE XARELTO

Do not take Xarelto

- **if you are allergic** (hypersensitive) to rivaroxaban or any of the other ingredients of Xarelto. The ingredients are listed at the end of this leaflet
- **if you are bleeding excessively**
- **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.

Take special care with Xarelto

- if you have **moderate or severe kidney disease**
- if you have **moderate liver 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)
 - **problems with the blood vessels in your brain or spinal column**
 - **a recent operation on your brain, spinal column or eye**

Tell your doctor before you take Xarelto, if any of these apply to you. Your doctor will decide, if you should be treated with Xarelto and if you should be kept under closer observation.

- Xarelto is **not recommended after an operation of a hip fracture.**
- **in children and adolescents**, Xarelto is **not recommended for people under 18 years of age.** There is not enough information on its use in children and adolescents.
- **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 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

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

- **If you are taking:**
 - some **medicines for fungal infections** (e.g. ketoconazole, itraconazole, voriconazole, posaconazole, fluconazole), unless they are only applied to the skin
 - some **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, because its effect may be increased. Your doctor will decide, if you should be treated with Xarelto and if you should be kept under closer observation.

- **If you are taking:**
 - some **medicines for treatment of epilepsy** (phenytoin, carbamazepine, phenobarbital),
 - **St Johns Wort**, a herbal product used for depression,
 - **rifampicin**, an antibiotic.

Tell your doctor before taking Xarelto, because its effect may be reduced. Your doctor will decide, if you should be treated with Xarelto and if you should be kept under closer observation.

Taking Xarelto with food and drink

Xarelto can be taken with or without food.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding do not take Xarelto. 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 Xarelto, immediately tell your doctor, who will decide how you should be treated.

Driving and using machines

No studies on the effects of Xarelto on the ability to drive and use machines have been performed. However, Xarelto may cause side effects such as dizziness or fainting. You should not drive or use machines if you are affected by these symptoms. For Xarelto, these side effects are uncommon (see section 4 “Possible side effects”).

Important information about some of the ingredients of Xarelto

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

3. HOW TO TAKE XARELTO

Always take Xarelto 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 tablet (10 mg) once a day.

Swallow the tablet preferably with water.

Xarelto can be taken with or without food.

When to take Xarelto

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.

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.

If you forget to take Xarelto

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

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

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

4. POSSIBLE SIDE EFFECTS

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

Like other similar medicines (antithrombotic agents), Xarelto may cause bleedings which may potentially be life threatening. 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 frequency of possible side effects listed below is defined using the following convention:

very common (affects more than 1 user in 10)

common (affects 1 to 10 users in 100)

uncommon (affects 1 to 10 users in 1,000)

rare (affects 1 to 10 users in 10,000)

very rare (affects less than 1 user in 10,000)

not known (frequency cannot be estimated from the available data).

Common side effects

- bleeding following your operation
- reduction in red blood cells which can make your skin pale and cause weakness or breathlessness
- feeling sick
- blood tests may show an increase in some liver enzymes

Uncommon side effects

- bleeding in your stomach or bowel, genital bleeding, nose bleed
- bleeding into tissue or a cavity of your body (haematoma, bruising)
- blood in your urine
- oozing of blood or fluid from surgical wound
- raised heartbeat
- low blood pressure
- feeling unwell (weakness, tiredness), headache, dizziness, fainting
- stomach ache, indigestion, constipation, diarrhoea, being sick

- dry mouth
- localised swelling, swelling in your limbs
- 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

Rare side effects

- impaired function of your liver
- allergic skin reactions

Side effects where frequency is not known

- bleeding into a critical organ (e.g. your brain)
- adrenal bleeding
- bleeding from the whites of your eyes
- coughing up blood
- yellowing of the skin and eye (jaundice)
- hypersensitivity

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE XARELTO

Keep out of the reach and sight of children.

Do not use Xarelto after the expiry date which is stated on the carton and on each blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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.

6. FURTHER INFORMATION

What Xarelto contains

- The active substance is rivaroxaban. Each tablet contains 10 mg of rivaroxaban.
- The other ingredients are:
Tablet core: microcrystalline cellulose, croscarmellose sodium, lactose monohydrate, hypromellose, sodium laurilsulfate, magnesium stearate.
Film coat: macrogol 3350, hypromellose, titanium dioxide (E171), iron oxide red (E172).

What Xarelto looks like and contents of the pack

The film-coated tablets are light red, round and marked with the BAYER-cross on one side and "10" and a triangle on the other side. They come in blisters in cartons of 5, 10, 30 and 100 tablets. Not all pack-sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Bayer HealthCare AG
D-51368 Leverkusen
Germany

For more information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

België / Belgique / Belgien

Bayer S.A./N.V.
Tél/Tel: +32 2 535 63 11

България

Байер България ЕООД
Тел: +359 02 81 401 01

Česká republika

Bayer s.r.o.
Tel: +420 2 71 73 06 61

Danmark

Bayer A/S
Tlf: +45 45 23 50 00

Deutschland

Bayer Vital GmbH
Tel: +49 214 30 513 48

Eesti

UAB Bayer Eesti filiaal
Tel: +372 655 85 65

Ελλάδα

Bayer Ελλάς ABEE
Τηλ: +30 210 618 75 00

España

Química Farmacéutica Bayer S.L.
Tel: +34 93 495 65 00

France

Bayer Santé
Tél: +33 3 20 20 80 80

Ireland

Bayer Limited
Tel: +353 1 299 93 13

Ísland

Vistor hf.
Sími: +354 535 70 00

Italia

Bayer S.p.A.
Tel: +39 02 397 81

Κύπρος

NOVAGEM Limited
Τηλ: + 357 22 74 77 47

Latvija

UAB Bayer Latvijas filiāle
Tel: +371 67 84 55 63

Lietuva

UAB Bayer, Bayer Schering Pharma
Tel: +37 05 23 36 868

Luxembourg / Luxemburg

Bayer S.A./N.V.
Tél/Tel: +32 2 535 63 11

Magyarország

Bayer Hungária KFT
Tel: +36 14 87 41 00

Malta

Alfred Gera and Sons Ltd.
Tel: +35621 44 62 05

Nederland

Bayer B.V., Bayer Schering Pharma
Tel: +31 297 28 06 66

Norge

Bayer AS
Tlf: +47 24 11 18 00

Österreich

Bayer Austria Ges. m. b. H.
Tel: +43 1 711 46 0

Polska

Bayer Sp. z o.o.
Tel: +48 22 572 35 00

Portugal

Bayer Portugal S.A.
Tel: +351 21 416 42 00

România

SC Bayer SRL
Tel: +40 21 528 59 00

Slovenija

Bayer d. o. o.
Tel: +386 1 58 14 400

Slovenská republika

Bayer, spol. s r.o.
Tel: +42 12 59 21 31 11

Suomi/Finland

Bayer Oy, Bayer Schering Pharma
Puh/Tel: +358 20 785 21

Sverige

Bayer AB
Tel: +46 8 580 223 00

United Kingdom

Bayer plc
Tel: +44 1635 563000

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