



Safety Information Card for Patients Under Anticoagulant Treatment with Xarelto®

Xarelto® 2.5 mg
Xarelto® 10 mg
Xarelto® 15 mg
Xarelto® 20 mg

Keep this card with you at all times
Present this card to every doctor or dentist at the beginning of the visit

The patient carrying this card is under anticoagulation treatment with Xarelto® (rivaroxaban)

Name _____

Address _____

Date of birth _____ Weight _____

Information regarding concomitant medications and diseases _____

Information in case of emergency

In case of emergency, please notify:

Doctor's name _____ Doctor's phone _____

Please also notify:

Name _____ Relationship _____

Phone _____

Emergency phone (Clinic/first aid) _____

Information regarding use of the medicine

Treatment start date _____

Indication _____

Dosage and administration regimen _____

Renal function at treatment onset (creatinine clearance mL/min)

Information for healthcare providers:

INR values should not be used as they are not a dependable measure of the anticoagulant activity of Xarelto.

Information on anticoagulants and guidance for the patient

- ◆ Xarelto® thins the blood, which prevents you from getting dangerous blood clots.
- ◆ Xarelto® must be taken exactly as prescribed by your doctor. To ensure optimal protection from blood clots you should strictly comply with the administration schedule as recommended by your doctor and never skip a dose, unless instructed by the doctor.
- ◆ You must not stop taking Xarelto® without first talking to your doctor as your risk of blood clots may increase.



Administration with food:

To ensure optimal treatment effectiveness:

- ◆ **Xarelto® 20 mg** must be taken with food.
- ◆ **Xarelto® 15 mg** must be taken with food.
- ◆ **Xarelto® 10 mg** can be taken with or without food.
- ◆ **Xarelto® 2.5 mg** can be taken with or without food.

The tablet should be swallowed with water. If you have difficulty swallowing the tablet whole, the tablet can be crushed and mixed with water or apple puree immediately before administration. For Xarelto® 15 mg and 20 mg, the crushed medicine should then be immediately followed by food.

If you forgot to take Xarelto® at the required time:

Xarelto® 10 mg, 15 mg and 20 mg:

- ◆ While taking Xarelto® 10/15/20 mg once daily – you should take a dose as soon as you remember. However, you should never take two doses on the same day!
- ◆ While taking Xarelto® 15 mg twice a day - [for the first 3 weeks for Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE) treatment] - take a dose as soon as you remember. Do not take more than two 15 mg tablets in a single day. Two 15 mg tablets can be taken together to obtain a dosage of 30 mg on one day. On the following day, carry on taking one 15 mg tablet twice a day.

In case of doubt consult your doctor.

Xarelto® 2.5 mg:

- ◆ While taking Xarelto® 2.5 mg – take the next dose at the usual time and consult your doctor. Do not take a double dose to make up for a missed dose.

- ◆ Tell the doctor about any other medicine that you are currently taking, have recently taken or intend to start taking, before you start treatment with Xarelto®. This instruction also includes non-prescription medicines, including non-steroidal anti-inflammatory drugs (NSAIDs) and nutritional supplements.
- ◆ Inform your doctor about Xarelto® intake prior to any surgery or invasive procedure, including dental treatments.
- ◆ When taking an anticoagulant such as Xarelto®, you should be aware of its possible side effects.
 - For a full list of side-effects please refer to the patient package insert.
 - Bleeding is the most common side effect.
 - Do not start taking Xarelto® if you know you are at risk of bleeding without first discussing this with your doctor.

Tell your doctor straight away if you have any signs or symptoms that could indicate bleeding, such as the following:

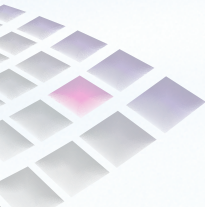
- Pain
- Paleness
- Unexplained swelling or discomfort
- Headache, dizziness, tiredness or exceptional weakness
- Breathlessness
- Chest pain or angina pectoris
- Unusual bruising, nosebleeds, bleeding of gums, bleeding from cuts that take a long time to stop
- Vaginal bleeding or menstrual flow that is heavier than normal
- Blood in the urine that may be pink or brown; red or black stools
- Coughing up blood, or vomiting blood or material that looks like coffee grounds

If you are at increased risk of bleeding, you should discuss this/consult with your doctor. The main risk factors for bleeding include, among others:

- Moderate or severe kidney disease
- Liver impairment
- If you are taking other medicines to prevent blood clotting e.g., non-steroidal anti-inflammatory drugs, aspirin and other anticoagulants
- Very high blood pressure, not controlled by medical treatment
- You are suffering from bleedings
- Disease of the stomach or bowel that might result in bleeding, e.g., inflammation of the bowel or stomach or inflammation of the esophagus due to, for example, gastroesophageal reflux
- Retinopathy
- Bronchiectasis or previous bleeding from the lung

Additional risk factors for bleeding for patients taking Xarelto® 2.5 mg:

- Age 75 years or older
- Weight of 60 kg or less
- Coronary artery disease with severe symptomatic heart failure



Reporting side-effects

Side-effects can be reported to the Ministry of Health using the portal for reporting side effects which can be found on the Ministry of Health website: www.health.gov.il

Or via the link: <https://sideeffects.health.gov.il/>

Additionally: side-effects and product quality complaints can be reported to Bayer Israel's Pharmacovigilance Unit:

E-mail: dsisrael@bayer.com, fax: 09-7626741

For additional information please refer to the Patient Package Insert.

In case of any questions, please refer to your treating doctor.

This Safety Information Card and its content were reviewed and approved by the Ministry of Health on 17-Dec-2019.

