

For patients taking (Xarelto®, rivaroxaban) for atrial fibrillation

Atrial fibrillation may cause blood clots to form in the atrium of the heart.

If these blood clots come loose and travel to the brain they may cause stroke.

Xarelto decreases the risk of blood clots and stroke by helping to prevent the clots from forming. This brochure explains what atrial fibrillation is and how treatment with Xarelto works and why it is important.

Causes of atrial fibrillation

In atrial fibrillation the heart beat is irregular and sometimes rapid because the sinus node that controls the electrical impulses to the atrium of the heart does not function properly. In a normal situation, the atria of the heart contract and fill both ventricles of the heart with blood. When the ventricles are filled they pump the blood into the body. This mechanism is usually coordinated and efficient, but in atrial fibrillation electrical impulses arise in many different places within the atria, causing irregular and inefficient contraction of the heart. The atria are unable to either fill or empty properly because they are fibrillating. This also leads to a lack of coordination between the action of the atria and the ventricles, causing the ventricles of the heart to pump blood less efficiently. The pulse may then be both weak and irregular, and sometimes also very quick.

Symptoms

The most common symptoms of atrial fibrillation are heart palpitations and irregular heart rhythm. Some people experience fatigue, have less energy and can more easily become short of breath, while others experience no symptoms at all.

Atrial fibrillation can be seen on ECG

The doctor uses an ECG to diagnose ongoing atrial fibrillation. If you are experiencing atrial fibrillation that comes and goes, a 24-hour or 48-hour ECG recorder may help make the diagnosis.

Three types of atrial fibrillation

Atrial fibrillation is usually divided into three types, depending on how long each episode of fibrillation lasts.

Paroxysmal atrial fibrillation – short episodes that usually last only a few minutes. Sometimes such episodes may last for a couple of days before the heart returns to a regular rhythm, known as sinus rhythm.

Persistent atrial fibrillation – episodes last longer than one week and may resolve spontaneously. Either medications or cardioversion may be needed to terminate the episode.

Chronic atrial fibrillation – atrial fibrillation that does not resolve.

Treatment of atrial fibrillation

Depending on the severity and duration of the problems, various types of treatment are available. To decrease the heart rate and prevent new episodes, treatment is usually initiated with beta-blockers.

Beta-blockers are drugs that help the heart to pump more calmly and efficiently. Sometimes beta-blockers alone are sufficient treatment, but not always, in which case the two most common options are:

Cardioversion – cardioversion entails administration of an electrical shock to the heart to restore sinus rhythm. The procedure requires a brief period of anesthesia.

Medications – if cardioversion is inappropriate or the attempt fails, antiarrhythmics may be used instead. Antiarrhythmics are medications that help the heart to re-establish and retain sinus rhythm.

Both of these treatment options require medication to prevent blood clots. Atrial fibrillation often entails lifelong drug treatment to prevent blood clots and stroke.

Atrial fibrillation and anticoagulants

Atrial fibrillation puts patients at an increased risk of blood clot and stroke. Fibrillation impairs the pump function of the heart, which means the blood moves less efficiently through the atria and ventricles. When blood flow through the heart is impaired, the risk of forming clots increases. If a blood clot or portion of a clot breaks loose and is carried by the blood stream into the body, it may lodge in the brain and cause a stroke. Treatment with anticoagulants (blood thinners) considerably reduces the risk of blood clot formation and thereby decreases the risk of stroke.

Xarelto

Xarelto belongs to a class of medications known as anticoagulants, medications to prevent blood clot formation. Xarelto reduces the ability of the blood to clot, thereby protecting against formation of blood clots. It works by blocking a specific factor in the blood – coagulation factor Xa.

Xarelto is a prescription drug.

Treatment with Xarelto

Duration of treatment

Treatment with Xarelto should continue as long as the risk of stroke remains.

Lifelong treatment is often required. Do not stop taking Xarelto without first speaking with your doctor since the risk of a blood clot may increase.

How to take Xarelto

Take Xarelto once daily. Try to take the tablet at the same time each day so it will be easier to remember. It is important to take Xarelto with food to provide maximum protection.

Food and drink

You may eat what you want; alcohol in moderation does not affect treatment.

If you forget to take a tablet

Try to take your tablet at the same time every day, such as with breakfast or dinner. If you forget to take your tablet, take it as soon as you remember it on the same day. If you miss a full day, continue on the following day as before with one tablet daily. Never double your dose to make up for a missed tablet.

If you take too much Xarelto

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

Possible side effects

All medications may cause side effects, though not all users are affected. Contact your clinic for advice if you notice bleeding from sites such as your nose, mouth, urinary tract or intestinal tract. Seek emergency care if you experience heavy bleeding or bleeding that does not stop by itself. If you experience a sharp blow to the stomach, chest or head, you should also seek emergency care to make sure you have no internal bleeding. Also seek emergency care if you experience unusual weakness, fatigue, pallor, dizziness, headaches, unexplained swelling, shortness of breath, chest pain or angina, symptoms that may be signs of bleeding.

Interaction with other medications

Do not take anti-inflammatory medications such as Voltaren, Naproxen or aspirin without first asking your doctor. You may take pain relievers containing paracetamol (acetaminophen) such as Alvedon or Panodil along with Xarelto. It is important that you inform your doctor about what other medications you may be taking, including over the counter medications and herbal medicinal products. Your doctor will decide what treatment is indicated.

Restrictions

Contact your doctor before taking Xarelto if:

- ◆ you are allergic (hypersensitive) to rivaroxaban or any other ingredient in Xarelto
- ◆ you have a lot of bleeding, or ongoing bleeding
- ◆ you have liver disease that puts you at increased risk of bleeding
- ◆ you are pregnant or nursing

Also contact your doctor if you plan to become pregnant.

Xarelto prior to elective surgery, biopsy or dental procedures

If you are going to have elective surgery, biopsy or a dental procedure such as tooth extraction, you should contact and inform your doctor or dentist that you are taking Xarelto.

Regular blood testing is not necessary

The effect of Xarelto does not differ significantly among individuals. Xarelto should be taken with food to ensure uptake of the drug, but no special dietary adjustments are necessary. Therefore you do not need regular blood testing to monitor the effect. By taking the same dose of Xarelto every day you will achieve the expected protection against blood clots and thereby reduce the risk of stroke.

Information card for your safety

You will receive a card from your doctor or nurse containing information about your treatment with Xarelto. You should always bring your card with you when visiting or receiving treatment from a doctor, dentist or other healthcare provider.

Do you have any questions about Xarelto?

Talk to your doctor or nurse at the clinic that handles your treatment.

For complete information, please see the package leaflet.

Would you like a daily reminder via text message? Register at www.xarelto-patient.se
Please note that this service is in Swedish.

Xarelto (rivaroxaban), antitrombotiskt medel, R (B01 AF01). Tabletter 15 mg och 20 mg (F). **Indikation:** Förebyggande av stroke och systemisk embolism hos vuxna patienter med icke-valvulärt förmaksflimmer med en eller flera riskfaktorer, såsom hjärtsvikt, hypertoni, ålder ≥ 75 år, diabetes mellitus, tidigare stroke eller transitorisk ischemisk attack. **Dosering:** rekommenderad dos 20 mg en gång dagligen, vilket också är den rekommenderade maxdosen. För patienter med nedsatt njurfunktion (kreatininclearance 15–49 ml/min) är den rekommenderade dosen 15 mg en gång dagligen. Behandling med Xarelto kan initieras eller fortskräda hos patienter som kan behöva konvertering. Rekommenderad dos för patienter med icke-valvulärt förmaksflimmer som genomgår PCI (perkutan koronarintervention) med stentinförläggning: Det finns begränsad erfarenhet om användning av reducerad dos, 15 mg Xarelto en gång dagligen (eller 10 mg Xarelto en gång dagligen för patienter med måttligt nedsatt njurfunktion [kreatininclearance 30–49 ml/min]) med tillägg av P2Y₁₂-hämmare i högst 12 månader till patienter med icke-valvulärt förmaksflimmer som behandlas med oral antikoagulation och som genomgår PCI med stentinförläggning. **Kontraindikationer:** Aktiv, kliniskt signifikant blödning. Organskada eller tillstånd, som anses utgöra en

ökad risk för större blödning. Samtidig behandling med andra antikoagulantia. Lever-sjukdom förknippade med koagulopati och kliniskt relevant blödningsrisk inklusive cirrhotiska patienter med Child Pugh B och C. Graviditet och amning. **Varningar och försiktighet:** Xarelto ska användas med försiktighet hos patienter med kreatininclearance 15–29 ml/min. Användning av Xarelto hos patienter med kreatininclearance < 15 ml/min rekommenderas inte. Om blödning inte kan kontrolleras kan antingen tillförsel av ett specifikt medel för reversering av faktor Xa-hämmare (andexanet alfa), som motverkar den farmakologiska effekten av rivaroxaban, eller ett specifikt prokoagulat medel, såsom protrombinkomplexkoncentrat (PCC), aktiverat protrombinkomplexkoncentrat (APCC) eller rekombinant faktor VIIa (r-FVIIa), övervägas. Datum för senaste översynen av produktresumén oktober 2019. Bayer AB. Box 606. 169 26 Solna. Tel. 08-580 223 00. För ytterligare information samt priser se www.fass.se. Före förskrivning vänligen läs produktresumén på fass.se.

▼ Detta läkemedel är föremål för utökad övervakning. Hälso- och sjukvårdspersonal uppmanas att rapportera varje misstänkt biverkning till Läkemedelsverket.

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