

- **How do I store my tablets?**

Do not take your tablets if the expiry date has passed. Keep the tablets in their original packaging and store them in a dry place below 25°C. Keep all medicines well out of the reach of children – it is best to lock them in a cupboard or medicine cabinet.

- **Will rivaroxaban interact with other medicines, food or alcohol?**

Rivaroxaban has fewer potential interactions with other medicines compared with warfarin, and at present there are no known interactions with specific foods or alcohol. There are some medicines that rivaroxaban does interact with so patients should inform their prescriber of the names of all medicines they are taking (including prescription and over-the-counter medicines, vitamins and herbal supplements).

- **Should patients stop taking rivaroxaban if they are going to have a dental or medical procedure?**

Patients should not stop taking rivaroxaban without first talking to their doctor or dentist. Rivaroxaban may need to be stopped for one or more days before any planned surgery, dental or medical procedure.

All patients should be given the rivaroxaban alert card and counselled on the details. This should be carried with them at all times.

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PATIENT INFORMATION LEAFLET

RIVAROXABAN FOR THE TREATMENT OF NON-VALVULAR ATRIAL FIBRILLATION

People with atrial fibrillation (AF) are at increased risk of having a stroke. If you have AF, your doctor should assess your individual risk of a stroke and discuss with you as to whether you should be started on medication to reduce this risk. This leaflet has been devised to provide information in conjunction with the advice from your doctor.

- **What is rivaroxaban for?**

Rivaroxaban (Xarelto®) is an anticoagulant (like warfarin) used to lower the risk of blood clots developing in patients who have a condition called atrial fibrillation (an abnormal heartbeat) as well as other risk factors for stroke. A blood clot which blocks an artery (blood vessel) is called an embolism. If the embolism occurs in the arteries of the brain it can cause a stroke. Anticoagulants slow down the time it takes for your blood to clot and reduce the risk of these events happening.

- **For patients with non-valvular atrial fibrillation, is it worth changing from warfarin?**

Warfarin has been prescribed for more than 60 years so there is plenty of experience of its clinical use. The clinical trial showed that rivaroxaban is as effective as warfarin. For patients whose warfarin is well controlled, it is probably not advisable to change. For patients who have poor anticoagulant control, a switch to rivaroxaban might be considered.

- **Does rivaroxaban cause less bleeding than warfarin?**

As both rivaroxaban and warfarin affect blood clotting, patients may still experience side effects such as bruising and bleeding. Intracranial bleeding (bleeding into the brain) is worrying because it is usually very serious. In the clinical trial, rivaroxaban caused less intracranial bleeding than warfarin.

Gastrointestinal (stomach and bowel) bleeding is also a concern as it varies widely in terms of severity and is more common. In the clinical trial, rivaroxaban caused more gastrointestinal symptoms than warfarin (e.g., indigestion, stomach ache). There was also more epistaxis (nose bleeds) and haematuria (blood in the urine) with rivaroxaban compared to warfarin.

- **If a patient has excessive bleeding, can the anticoagulant effect of rivaroxaban be reversed?**

There is no licensed product currently available to reverse bleeding with rivaroxaban. However, if urgent treatment is required, rivaroxaban will be discontinued, and supportive measures will be started. It is easier to manage major bleeding in patients on warfarin.

- **Are regular blood tests needed to monitor rivaroxaban levels?**

There is no need for regular blood tests to measure the level of anticoagulant control with rivaroxaban. However, a blood test is needed to measure how well the kidneys are working before starting treatment and then at least once a year whilst on rivaroxaban treatment.

- **When and how do I take this medicine?**

Always take this medicine as your doctor has told you. If you do not take rivaroxaban regularly it will not be effective and your risk of a clot forming will increase.

The dose is usually 20mg once a day. This dose may be reduced to 15mg once a day if you have kidney problems, are taking other

medicines which interact or have a higher risk of bleeding. Your doctor will discuss this with you.

Rivaroxaban should be taken with a meal preferably with water. Rivaroxaban may be re-dispensed into a compliance aid if necessary.

- **What are the possible side effects of this medicine?**

As this medicine affects blood clotting, most side effects are related to signs such as bruising or bleeding. Tell your doctor immediately if you experience any of the following side effects: Long or excessive bleeding, exceptional weakness, tiredness, paleness, dizziness, headache or unexplained swelling. Also report if there is any blood in the urine or passing black tarry or blood-stained stools.

Patients should seek urgent medical attention if they fall or injure themselves during treatment, especially if they hit their head, due to the increased risk of bleeding.

- **What should I do if I forget to take a dose?**

It is important not to skip doses. If a dose is missed the patient should take rivaroxaban immediately and continue on the following day with the once daily intake as recommended. The dose should not be doubled within the same day to make up for a missed dose.

- **What should I do if I take too many tablets?**

If you have taken too many tablets all at once, you may have an increased risk of bleeding. Contact your doctor or local hospital casualty department at once. Show the doctor your pack of tablets.