

- **How do I store dabigatran?**

Do not take your tablets if the expiry date has passed (you can find this information on the tablet box). Keep the tablets 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. **Dabigatran cannot be re-dispensed in a compliance aid or blister pack.** If you usually have your medications in a compliance aid or blister pack, please speak to your pharmacist.

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

There are no known interactions with specific foods or alcohol. However, excessive alcohol consumption can increase your risk of bleeding, so it is advisable not to drink more than 14 units each week. There are some medicines that dabigatran does interact with so please let anybody prescribing you medicines know the names of all medications you are taking (including prescription and over-the-counter medicines, vitamins and herbal supplements).

- **Should I stop taking dabigatran if I am going to have a dental or medical procedure?**

Do not stop taking dabigatran without first talking to your doctor or dentist. Dabigatran may need to be stopped for one or more days before any planned surgery, dental or medical procedure.

You will receive a dabigatran alert card (contained within the tablet box). Please carry this with you at all times.

PATIENT INFORMATION LEAFLET

DABIGATRAN FOR THE TREATMENT OF ATRIAL FIBRILLATION

People with atrial fibrillation have a five times higher risk of having a stroke. If you have atrial fibrillation, your doctor should assess your individual risk of a stroke and discuss whether you should be started on medication to reduce this risk.

- **What is dabigatran for?**

Dabigatran etexilate (Pradaxa®) is an anticoagulant, sometimes referred to as a 'blood thinner', used to lower the risk of blood clots developing in people who have atrial fibrillation (an irregular heartbeat) and other risk factors for stroke. Having atrial fibrillation increases the risk of a blood clot forming in the heart. If this clot travels to the brain, it may cause a stroke. Taking dabigatran slows down the time it takes for your blood to clot and reduces the risk of this happening.

- **For people with atrial fibrillation, is it worth changing from warfarin to dabigatran?**

Warfarin has been prescribed for more than 60 years so there is plenty of experience of its clinical use. There is evidence that dabigatran is as effective as warfarin at preventing a stroke. If warfarin is not well controlled your GP or healthcare specialist may recommend changing from warfarin to reduce the risk of a stroke.

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

As both dabigatran and warfarin affect blood clotting, people may still experience side effects such as bruising and bleeding.

Evidence has shown that dabigatran has a lower risk of intracranial bleeding (bleeding into the brain) than warfarin. Intracranial bleeding (bleeding into the brain) is worrying because it is usually very serious.

Gastrointestinal (stomach and bowel) bleeding is also a concern as it varies widely in terms of severity and is more common. Evidence shows that dabigatran at the 150mg dose has a higher risk of gastrointestinal (stomach and bowel) bleeding than warfarin. Evidence shows that dabigatran caused more gastrointestinal symptoms than warfarin (e.g., indigestion, stomach-ache). Please seek medical advice if you have any blood in your faeces or vomit.

- **In the event of excessive bleeding, can the effect of dabigatran be reversed?**

There is a drug called Idarucizumab that can be used to reverse bleeding in people taking dabigatran. If urgent treatment is required for bleeding, dabigatran will be stopped, and you may be given this drug.

- **Are regular blood tests needed to monitor dabigatran?**

There is no need for regular blood tests with dabigatran. However, a blood test is needed to measure how well the kidneys and liver are working before starting treatment and then at least once a year while on treatment.

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

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

The dose is usually 150mg twice daily morning and night. A reduced dose of dabigatran (110mg twice daily) may be prescribed in some circumstances (older age, high bleed risk, prescription of other medications that may affect dabigatran).

Dabigatran can be taken with or without food. The capsule should be swallowed whole with some water. Do not break, chew, or empty pellets from the capsule, as this may increase the risk of bleeding.

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

As this medicine slows down the time it takes for your blood to clot, most side effects are bruising or bleeding. Tell your doctor immediately if you experience any of the following: long or excessive bleeding, exceptional weakness, tiredness, paleness, dizziness, headache, or unexplained swelling. Also report if there is any blood in your urine, or if you pass black tarry or blood-stained stools.

You should seek urgent medical attention if you fall or injure yourself whilst taking dabigatran, especially if you hit your 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, you should take dabigatran as soon as you remember as long as your next dose is more than 6 hours away. Then take your next dose at the usual time. If the next dose is less than 6 hours away, the missed dose should not be taken. The dose should not be doubled to make up for a missed dose.

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

If you have taken too many capsules at once, you may have an increased risk of bleeding. Contact your doctor immediately. Take your medication with you to show the doctor.