

- **How do I store dabigatran?**

Do not take your capsules if the expiry date has passed. Keep the capsules 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 dabigatran interact with other medicines, food or alcohol?**

Dabigatran 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 dabigatran 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 dabigatran if they are going to have a dental or medical procedure?**

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

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

*Acknowledgment to NHS Scotland: Frequently asked questions ~ the introduction of dabigatran etexilate (Pradaxa®) April 2012.*

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## PATIENT INFORMATION LEAFLET

### DABIGATRAN 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 dabigatran for?**

Dabigatran etexilate (Pradaxa®) 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 heart beat) 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 when warfarin is used well (good INR control as measured by blood tests), it is as effective as dabigatran. For patients whose warfarin is well controlled, it is probably not advisable to change. For patients who have poor anticoagulant control, dabigatran reduced the number of strokes and therefore a switch to dabigatran might be considered.

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

As both dabigatran 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 a recent clinical trial, dabigatran 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 a recent clinical trial, dabigatran caused more gastrointestinal symptoms than warfarin (e.g. indigestion, stomach ache) and more seriously, gastrointestinal bleeding, particularly in people over 75 years of age. If a patient is older than 75 or has an increased risk of bleeding, dabigatran could be prescribed at a reduced dose or may not be prescribed at all.

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

Yes. There is a specific reversal agent available for dabigatran. It can be used if there is severe bleeding or if emergency surgery or procedure is needed.

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

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

The dose is usually 150mg twice daily morning and night. This dose should be reduced to 110mg twice daily if you are 80 years or older or on verapamil. The lower dose of 110mg twice daily may be

considered for patients over 75 years old, taking other medicines which interact (e.g., amiodarone) or have a higher risk of bleeding.

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 since this may increase the risk of bleeding.

- **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.

In the clinical trial the rate of heart attacks with dabigatran was numerically higher than with warfarin. Your doctor will assess if dabigatran is appropriate if you have a history of heart attacks.

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. A missed dose of dabigatran may still be taken up to 6 hours prior to the next scheduled dose. If the next dose is less than 6 hours away the missed dose should not be taken. Never take double the dose to make up for missed doses.

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

If you have taken too many capsules 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 capsules.