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Dabigatran etexilate

This factsheet is intended to help those affected by atrial fibrillation (AF) understand the medication dabigatran, with a brief introduction to how it works, dosing and side effects.

AF and stroke risk

People who have AF are at higher risk of clots forming in the heart. If your heartbeat is irregular and fast, your heart may not have a chance to empty properly before filling up with blood again. Blood can collect inside the upper chamber of the left side of the heart (the left atrium), and this increases the risk of blood clots forming. If these clots travel through the bloodstream to the brain then this may cause a stroke.

AF-Related strokes are often more serious than other strokes . This is because the large clots which form in the heart can cause more damage resulting in more disability.

To reduce the risk of stroke an anticoagulant is often prescribed. An anticoagulant lengthens the time a clot takes to form by just enough to address any risk of stroke.

Until recently warfarin was the most commonly prescribed anticoagulant and is a very effective medication, dramatically reducing the risk of stroke. Warfarin requires regular monitoring as its effectiveness can vary due to lifestyle, dietary intake, general health and other prescribed medications. Monitoring involves a blood test to check international normalised ratio (INR) levels. The result determines the dose of warfarin.

In recent years further anticoagulants have been developed. These are the direct oral anticoagulants (DOACs), and include dabigatran rivaroxaban, apixaban and edoxaban. Unlike warfarin, they do not require blood tests as they are unaffected by dietary intake, lifestyle or general health. DOACs also interact less with other medications.

The DOACs are as effective as warfarin in preventing an AF-Related stroke.

How it works

The National Institute for Health and Care Excellence (NICE) approved the use of dabigatran in March 2012 for the prevention of stroke and systemic blood clots in patients with AF.

Dabigatran is a medication that has a direct effect on the enzyme thrombin - it is called a direct thrombin inhibitor. It has its effects on the final step of the 'clotting cascade' when fibrinogen is converted to fibrin; here it thins the blood in order to reduce the risk of clots forming. Dabigatran is currently licensed for stroke prevention in AF in the UK; it is specifically licensed in patients with non-valvular AF without underlying heart valve disease, who have at least one or more risk factors.

It is also licensed for the treatment of deep vein thrombosis and pulmonary embolism, and as a preventive measure for these conditions. Unlike warfarin, dabigatran doesn't require regular blood tests to determine the dose.

Dabigatran is also used in medical practice to reduce the risk of clots forming after orthopaedic surgery, such as a hip or knee replacement.

Dose

The recommended dose of dabigatran is 150mg twice daily. If you are over 80, have low body weight or impaired kidney function, you may be offered a lower dose of 110mg twice daily.

In December 2015, idarucizumab (Praxbind); a dabigatran specific reversal agent was launched in the UK for emergency surgery or urgent procedures; and in uncontrolled bleeding. The use of Praxbind is restricted to hospital use only.

Assessments on suitability for dabigatran should be made in light of your medical history, your

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assessed AF-stroke risk and in line with NICE guidance (CG180 and TA249).

If you are currently taking an alternative anticoagulant to reduce your risk of AF-stroke, then switching to dabigatran may be considered if you are experiencing side-effects with your current anticoagulant, or if you have poor INR control (in the case of warfarin); however all changes in medication need to be discussed and agreed with your clinician to ensure that the most appropriate therapy for you is prescribed.

In 2014, NICE recommended that all approved anticoagulants be placed alongside each other as a first line treatment for stroke prevention in AF. In other words, dabigatran, rivaroxaban, edoxaban and apixaban should not be reserved just for patients for whom warfarin is unsuitable.

What should I do if I miss a dose?

Unlike warfarin, dabigatran is rapidly metabolised by the body, requiring a twice daily dose. If a tablet is missed or overlooked then it should be taken as soon as possible after the mistake is noticed, unless it is almost time for your next dose. Please check the patient information leaflet which comes with the medication for further details. Double or extra doses of dabigatran should not be taken.

Dabigatran requires acidic surroundings to help be absorbed, which is why you may find it causes indigestion problems. You are advised to swallow the capsules whole with a glass of water.

In common with other anticoagulants, if you are on dabigatran you may find that you bruise easily and will bleed for slightly longer if scratched or cut.

In one study, heart attack (myocardial infarction) rates in patients taking warfarin was marginally lower than dabigatran.

What to do if you notice bleeding

Speak to your doctor immediately if you experience any of the following signs of bleeding:

- Bruising or bleeding under the skin
- Nose bleeds or cuts that take a long time to stop bleeding
- Red or dark brown urine
- Coughing up or vomiting blood or ground coffee-like material
- Red or black stools
- Bleeding gums
- Bleeding that does not stop by itself
- Abnormally heavy periods

Bleeding is not always obvious. If you experience any side effects talk to your doctor or pharmacist. It is important not to stop taking dabigatran without talking to them first.

For further information on anticoagulants, please see AF Association's Preventing AF-Related stroke: anticoagulation booklet.

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