Dabigatran (Pradaxa) for preventing stroke in people with atrial fibrillation

This Medicine Update is for people with atrial fibrillation who are taking, or thinking about taking, dabigatran.

Summary

Dabigatran is a medicine to help prevent a stroke in people with a condition called atrial fibrillation.

People with atrial fibrillation are more likely to develop a blood clot in their heart. The blood clot can then move to the brain and cause a stroke.

Dabigatran reduces the tendency of blood to clot and, in turn, the risk of having a stroke. It belongs to a group of medicines called anticoagulants.

Dabigatran is an alternative to warfarin for preventing strokes. As with other anticoagulant medicines, there is a risk of serious bleeding. Some serious bleeds may be life-threatening.

Dabigatran is a capsule that you take twice a day. For most people there is a standard dose. There is no need for a blood test to monitor how well it’s working or to adjust the dabigatran dose as there is with the standard anticoagulant treatment, warfarin.

Because dabigatran is a new medicine, the full range of potential side effects is not yet known.

www.nps.org.au/medicineupdate
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## Asking the right questions about new medicines

**What is Medicine Update?**

*Medicine Update* provides independent information about new medicines and new listings on the PBS. It tells you about the possible benefits and harms of new medicines, who can and can't use them, and some of the other treatment options available.

**How to use Medicine Update**

*Medicine Update* is a tool to help you understand your treatment choices and to discuss them with your doctor. *Medicine Update* doesn't describe all possible side effects, precautions, or interactions with other medicines — so you should always read the consumer medicine information (CMI) leaflet (see back page).

**Who is it for?**

*Medicine Update* is for anyone who is starting this medicine or thinking of starting it, and their carers.

**Where does Medicine Update come from?**

*Medicine Update* is written by NPS: Better choices, Better health in consultation with consumers and health professionals. NPS is an independent, not-for-profit, government-funded organisation.

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This information is not intended to take the place of medical advice and you should seek advice from a qualified health professional. Reasonable care is taken to ensure that this information is accurate at the date of creation. Where permitted by law, NPS disclaims all liability (including for negligence) for any loss, damage or injury resulting from reliance on or use of this information.
1. What dabigatran is

The active ingredient of this medicine is dabigatran (pronounced da-BIG-a-tran). It is also known by the brand name Pradaxa.

The active ingredient is the chemical in the medicine that makes the medicine work. Many medicines are known by their brand names as well as by the name of the active ingredient. Some medicines are available under several different brand names.

2. What dabigatran is for

People with atrial fibrillation are at greater risk of having a stroke than other people.

Dabigatran is used to help prevent a stroke in people with atrial fibrillation.

How does atrial fibrillation contribute to your risk of stroke?

Atrial fibrillation is a fast, irregular heartbeat that can lead to a blood clot forming in the heart. If the blood clot moves from the heart to the brain, it can block small blood vessels and cause a stroke.

Dabigatran can also be used after hip or knee surgery. You can read more about dabigatran after hip or knee surgery at www.nps.org.au/consumers/publications/medicine_update/issues/dabigatran

3. Who can take dabigatran

You can be prescribed dabigatran for stroke prevention if:

• you have an irregular heartbeat called atrial fibrillation, and
• your atrial fibrillation is not due to heart valve disease or heart valve replacement surgery, and
• your doctor finds that you have one or more of the other risk factors for stroke.

But dabigatran may not be suitable for you if you have:

• a medical condition that increases your likelihood of bleeding
• reduced kidney function
• liver problems.

Your doctor will need to take these into consideration before prescribing dabigatran.

Talk with your health professional about all the treatment options for preventing stroke.

Other factors that can increase your risk of stroke are:

• heart failure
• high blood pressure
• being over 75 years of age
• diabetes
• a previous stroke or blood clot (systemic embolism).
4. **How to take dabigatran**

It is important that you take dabigatran twice a day — one capsule in the morning and one at night.

Swallow the dabigatran capsule with water. It can be taken with or without food.

Do not chew the dabigatran capsule or break it open.

Talk to your doctor or pharmacist if you forget to take your dabigatran capsule. Do not take a double dose as this will increase your chance of bleeding.

**What is the dose?**

Unlike warfarin, there is a standard dose for most people.

The standard strength capsule contains 150 mg of dabigatran.

A lower strength 110 mg capsule may be prescribed for:

- people aged over 75 years who have a higher chance of side effects
- people with kidney problems
- those with a high risk of bleeding.

**How long will I need to take dabigatran for?**

Dabigatran for the prevention of stroke is likely to be a long-term treatment.

You should not stop taking dabigatran unless your doctor advises you to.

5. **What does dabigatran do?**

Dabigatran helps prevent a stroke in people with atrial fibrillation by reducing the chances of a blood clot forming.

Dabigatran is a type of medicine called an anticoagulant.

Anticoagulants reduce the tendency of blood to clot.

It’s important to note that dabigatran doesn’t treat the fast, irregular heartbeat of atrial fibrillation. Your doctor will prescribe other medicines or treatments for this.

6. **Important side effects to consider**

**Bleeding is a serious side effect**

The most significant risk for dabigatran and other anticoagulant medicines is bleeding (see section 9: *Serious bleeding is a risk with dabigatran and warfarin*). Some serious bleeds may be life-threatening.

You should seek urgent medical attention if you have:

- bleeding that won’t stop
- a nosebleed lasting for more than 10 minutes
- unexplained or severe bruising.

Internal bleeding is harder to detect. Contact your doctor immediately or go to the emergency department at your nearest hospital if you experience any of the following:

- blood in your urine
- red or black faeces
- feeling light headed or dizzy
- headaches that are unusual for you.

If you experience any serious injury, you are at greater risk of internal bleeding. You must get immediate medical attention, particularly if you hit your head.

**Anticoagulants are sometimes called blood thinners.**

For a list of all possible side effects, see the consumer information (CMI) leaflet for Pradaxa (dabigatran).

Ask your doctor about the possible side effects of dabigatran before you take it.

You can also discuss side effects with a pharmacist, by calling the Adverse Medicines Event (AME) Line on 1300 134 237 (Mon–Fri, 9pm–5pm).
6. **Important side effects to consider... continued**

**Indigestion is very common**
Dabigatran can cause indigestion.
Speak to your health professional about ways to manage indigestion if it affects you. For example, taking dabigatran with food may help.

**Dabigatran is a new medicine, so not all side effects are known**
Dabigatran has been tested in clinical trials, but the full range of potential side effects is not yet known. You should be aware of this and see your doctor straight away if you have any changes in your health or unusual symptoms after starting dabigatran.

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The terms *very common*, *common* and *uncommon* are used to describe the chance of getting a side effect. This is what they mean:
- **very common** — more than 1 in 10 people may get this side effect
- **common** — up to 1 in 10 people get this side effect
- **uncommon** — up to 1 in 100 people get this side effect.

A clinical trial is a research study conducted with patients, which compares one treatment with one or more other treatments, to assess its effectiveness and safety.

To find out more about clinical trials, see *What are clinical trials and why are they important?* at www.nps.org.au/medicinewise_choices

7. **What else you should know about dabigatran**

Do not stop taking dabigatran without talking to your doctor. This puts you at greater risk of developing a blood clot and having a stroke.

**Check before taking any other medicine**
Dabigatran interacts with some other medicines, but it doesn’t appear to interact with foods.
If you are taking dabigatran, you should talk to your doctor or pharmacist before taking any other medicine, including those from a supermarket or health food store.
Medicines that can interact with dabigatran and increase your risk of bleeding include:
- clopidogrel (Iscover, Plavix) — which is also used to thin the blood
- itraconazole (Sporanox) and ketoconazole tablets (Nizoral) for fungal infections
- aspirin
- ibuprofen (Advil, Brufen, Nurofen), diclofenac (Fenac, Voltaren), naproxen (Naprosic, Naproleve) and celecoxib (Celebrex) for pain and inflammation
- St. John’s wort.
Paracetamol (Panadol, Panamax) does not interact with dabigatran and can be used to treat headache, pain or fever.

**Let your health professional know that you take dabigatran**
Tell your doctor, pharmacist and dentist that you’re taking dabigatran. They may need to talk to the doctor who prescribed dabigatran for you, particularly if you need to have surgery.

An interaction is when another medicine, food or drink (including alcohol) changes how strongly a medicine works, or changes its side effects in some way.

The interaction may be with a food or food supplement, another prescription or over-the-counter medicine, or a natural or herbal remedy.
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8. Other medicines for preventing stroke caused by atrial fibrillation

Warfarin has been used to prevent stroke for over 50 years. It is very effective, but it may take some time to get the dose right.

If you take warfarin, you need to have a regular blood test (called an INR test) to monitor its effect.

If your INR is too high, your blood is taking too long to clot and your risk of bleeding increases. If it is too low, your blood is clotting too quickly. Your warfarin dose may need to be adjusted based on your results.

Your INR is affected by many other medicines as well as certain foods. If you have started taking warfarin, you need to be careful not to make big changes to your diet.

9. How to decide between dabigatran and warfarin

Your doctor will help you weigh up the potential benefits and harms of dabigatran and warfarin.

Dabigatran is effective for preventing strokes

In clinical trials, dabigatran prevented more strokes overall than warfarin. However, because warfarin is very effective, the improvement with dabigatran was small.

But there are people who should probably stay on warfarin

People who took their warfarin regularly in clinical trials — and had good blood test (INR) results — appeared to be less likely to benefit from switching to dabigatran.

So bear this in mind if you are doing well on warfarin therapy.

Some may find dabigatran more convenient

People taking dabigatran do not need regular blood tests, whereas people taking warfarin do.

Some people find these tests bothersome. But others like the opportunity to discuss their progress with their health professional and check that the warfarin is working.

Fewer medicines interact with dabigatran than with warfarin. And, unlike warfarin, there are no dietary restrictions with dabigatran.

Serious bleeding is a risk with dabigatran and warfarin

Serious bleeding needs urgent hospital treatment because it may be life-threatening.

In a clinical trial comparing dabigatran with warfarin, the number of people who had a serious bleed each year was similar with both medicines — about 3 or 4 out of every 100 people (3% to 4%).

But remember — you will only be prescribed dabigatran or warfarin if the benefit is thought to outweigh the risk of serious bleeding.

Doctors are familiar with using warfarin

Warfarin has been used for many years so its benefits and side effects are well known. Dabigatran is a very new medicine, and less is known about its long-term safety.

Warfarin’s effect can sometimes vary, so it’s important to have regular blood tests to make sure that it’s working well. Studies have shown that dabigatran’s effect is more predictable, so regular blood tests aren’t needed.
Dabigatran (Pradaxa) for preventing stroke in people with atrial fibrillation

10. Dabigatran availability

Dabigatran is used in two different ways:
- to prevent stroke in people with atrial fibrillation, and
- to prevent blood clots forming in the leg veins after hip or knee replacement surgery.

Dabigatran is currently covered by the Pharmaceutical Benefits Scheme (PBS) when it is prescribed for short-term use to prevent blood clots forming after hip or knee replacement surgery.

Most medicines prescribed by your doctor are covered by the Pharmaceutical Benefits Scheme (PBS). This means that the Australian Government pays part of the cost of your medicine.

You will need to pay the full price if the medicine is not available on the PBS, or is not available on the PBS for your specific condition.

For more information, see www.pbs.gov.au
11. Other ways to prevent stroke

Some of the risk factors for stroke, like age, gender and medical conditions (such as atrial fibrillation), are things you can’t change. However, there are several lifestyle-related risk factors that you can control.

**Know your personal risk factors**
Your doctor can help you monitor and manage medical conditions that increase your risk of having a stroke. These include high blood pressure, diabetes and high blood cholesterol.

**Be physically active and exercise regularly**
Keeping fit is important for so many aspects of your health. You don’t need to take part in organised sport or exercise classes to do this. Just walking or generally being more active will be of benefit.

Remember that if you are taking dabigatran or warfarin you need to be careful to avoid activities that increase your risk of injury.

**Keep to a healthy diet**
Fresh rather than processed foods are much better for you. A healthy diet has lots of different vegetables, fruit and whole grains and limits the amount of sugary, salty and fatty foods.

**Limit alcohol consumption**
People who drink heavily are three times more likely to have a stroke. Limit your alcohol intake to two drinks a day and have at least two alcohol-free days every week.

**Stop smoking**
Smoking is a major risk factor for stroke. If you smoke, get help to stop now. Talk to your doctor or call Quitline on 137 848.

Second-hand smoke from other people’s cigarettes is also harmful and you should try to avoid it.

**Learn to recognise the warning signs of a stroke and how to take action**
The FAST test is an easy way to remember and recognise the signs of stroke. FAST stands for Face, Arms, Speech and Time to act.

- **Face** — Check their face. Has their mouth drooped?
- **Arms** — Can they lift both arms?
- **Speech** — Is their speech slurred? Do you understand them?
- **Time** — Is critical.

If you see any of these signs, **call 000 straight away**.

The signs of stroke may occur alone or in combination and they can last a few seconds or up to 24 hours and then disappear.

The Stroke Foundation (www.strokefoundation.com.au) has more information about the risk factors for stroke and how it can be prevented.
Where to find more information

Read the consumer medicine information (CMI) leaflet
The CMI for Pradaxa (dabigatran) will tell you:

• who should not use the medicine
• how to take the medicine
• most of the possible side effects
• the ingredients

You can get the CMI leaflet for Pradaxa from:
• your doctor or pharmacist
• CMI search on the NPS website
• Boehringer Ingelheim, the makers of Pradaxa (dabigatran), on 1800 226 315.

Information over the phone
NPS works with healthdirect Australia to provide consumers with information on medicines.

To get information about dabigatran, call 1300 MEDICINE (1300 633 424) from anywhere in Australia for the cost of a local call (excluding mobiles). This service is available Monday to Friday, 9am–5pm EST, with the exception of NSW public holidays.

To report a side effect with dabigatran
Call the Adverse Medicines Event (AME) Line on 1300 134 237 (Monday to Friday, 9am–5pm EST).

The AME Line lets you report and discuss side effects that might be related to your medicine. The side effects of your medicine — but not your personal details — are reported to the Australian medicines regulatory agency (the Therapeutic Goods Administration or TGA for short). The information helps to improve the safe use of medicines.

For more information about the AME Line, visit www.nps.org.au/ame_line

More about using medicines wisely
For more information on how to make wise choices about taking medicines, see Medicinewise choices at www.nps.org.au/medicinewise_choices


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