

Pradaxa Information Guide

For people living with
non-valvular atrial fibrillation




Note: this booklet does not replace the advice of a qualified healthcare professional. Nor does it replace the Pradaxa Consumer Medicine Information (CMI), which is available from your Pharmacist or at www.ebs.tga.gov.au.

If you have any questions about your condition or its treatment, talk to your doctor.



**Boehringer
Ingelheim**



Card positional
55mm x 85mm

ABOUT THIS BOOKLET

This booklet contains important information about your diagnosis of non-valvular atrial fibrillation and your treatment with Pradaxa. It is designed to help you understand your diagnosis of non-valvular atrial fibrillation and the medication prescribed by your doctor to help prevent stroke, Pradaxa.

It also contains some useful information and tips on how you can work with your healthcare team to obtain the best possible results.

Please read it carefully and keep it safe in case you need to refer to it later.

Please note that this booklet does not replace the advice of your doctor. If you have any questions about your treatment, ask your doctor.

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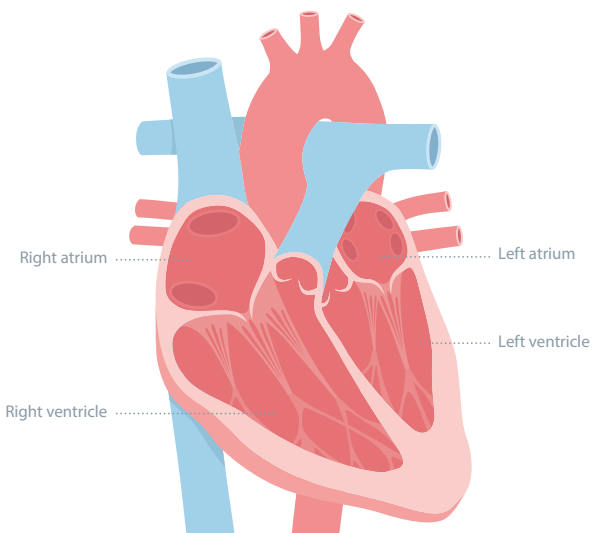
Living with non-valvular atrial fibrillation

What is non-valvular atrial fibrillation?

Atrial fibrillation is a type of arrhythmia, which means that the heart beats irregularly.

Non-valvular atrial fibrillation (NVAf) refers to a type of arrhythmia that starts in one of the four chambers of the heart (see diagram below that shows the parts of the human heart).

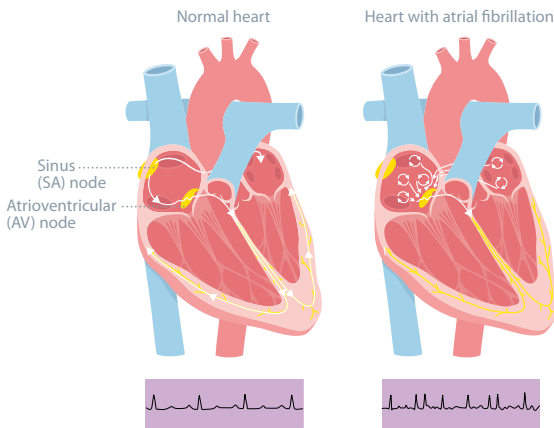
The Human Heart



What causes atrial fibrillation?

The heart has a natural pacemaker that sends out a regular, rhythmic, electrical signal that causes the heart muscle to contract, and thus pump blood around the body.

In atrial fibrillation, this signal isn't conducted through the heart properly, and as a result the muscle doesn't completely contract, leading to an abnormal heart beat (see image below).



This is usually the result of another chronic illness such as:

- Chronic high blood pressure (hypertension);
- Coronary heart disease;
- Heart valve diseases that interfere with the direction of blood flow in the heart; or
- An overactive thyroid gland (hyperthyroidism).

Atrial fibrillation can also be caused by:

- Chest surgery;
- Chest trauma;
- Certain prescription drugs; or
- Some illnesses such as pneumonia.

What are the symptoms of atrial fibrillation?

Symptoms of atrial fibrillation may come and go. Some people with atrial fibrillation have no symptoms at all, while others may experience some of the symptoms below:



Palpitations (your heart beats too hard, fast, or irregularly)



Shortness of breath



Weakness or problems exercising



Chest pain



Dizziness or fainting



Fatigue (tiredness) and confusion

How does atrial fibrillation increase my risk of stroke?

Atrial fibrillation causes your heart to beat irregularly and means your blood is not pumping as efficiently as it should.

This can slow blood flow through the heart, causing it to pool in the upper left chamber (atrium) of the heart, potentially forming a clot.

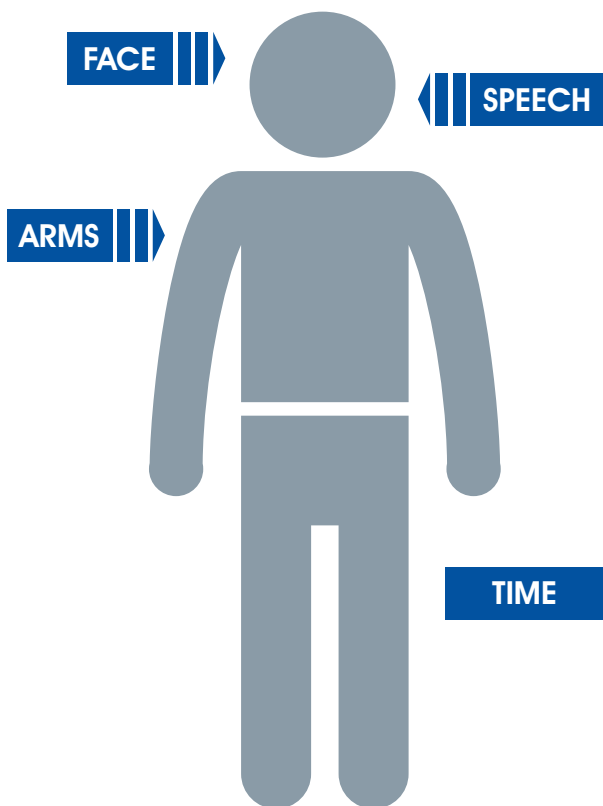
These clots can circulate with your blood to other parts of your body, including your brain. If the clot gets stuck in a blood vessel in your brain, it can cut off the blood supply, causing a stroke.



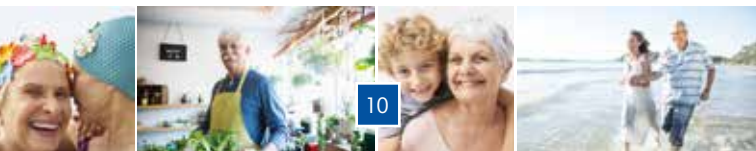
Being diagnosed with atrial fibrillation can be an alarming experience. Without treatment, the risk of having a stroke is up to seven times higher than someone who doesn't have atrial fibrillation.*

*The National Stroke Foundation 2010. The economic costs of atrial fibrillation in Australia. Available at: <http://www.atrialfibrillation-au.org>. Accessed June 2016.

How do I know if I'm having a stroke?



Adapted from the National Stroke Foundation FAST Stroke Symptoms.
Available at: www.strokefoundation.com.au/about-stroke/stroke-symptoms.
Accessed May 2016.



F

Your face may start to droop during a stroke.

A

You may lose sensation in one or both arms.

S

Your speech may be slurred and you may have difficulty understanding people.

T

Time is critical.
If you experience any of these symptoms call 000 immediately.



What are anticoagulants?

As you have already read, atrial fibrillation increases your risk of blood clots forming. Anticoagulants are a type of medicine that work by preventing blood clots from forming and reduce the risk of stroke. They are also sometimes called blood thinners.

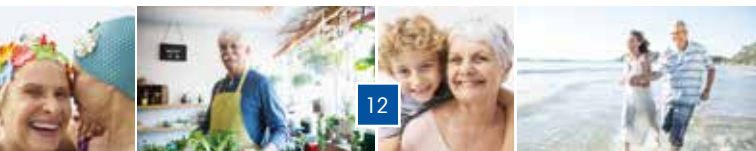
Are there any risks associated with anticoagulants?

All medications have some risks associated with them. Some are serious, some are not. The main risk associated with anticoagulants is bleeding.

Signs of bleeding

Signs of serious bleeding include:

- Severe bruising that gets worse;
- Any bleeding that takes a long time to stop;
- Unexplained bleeding or bruising (for example, bruises on your back and chest where you haven't injured yourself); or
- Menstrual bleeding that is much heavier than usual, or unexplained vaginal bleeding.



Less obvious signs of serious bleeding include:

- Dark red or brown urine;
- Red, dark brown, or black bowel motions;
- Coughing up blood;
- Bloody or dark-stained vomit;
- Severe headache or dizziness;
- Weakness or lethargy;
- Unusual pain, swelling, or discomfort; or
- Any difficulty breathing.

If you have any concerns about your medication, talk to your doctor.



If you develop excessive or uncontrollable bleeding, go to your nearest emergency department or call 000 immediately. Tell the staff at the hospital or the ambulance officers what medications you're taking.



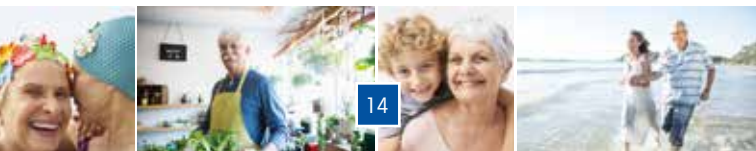
What about taking other medications with anticoagulants?

Some over the counter medications (e.g. aspirin) also have an anticoagulant effect. You should not take these medicines with your anticoagulant unless on your doctor's advice.

If you have any questions about taking other medications while taking anticoagulants, ask your doctor or pharmacist.

What else can I do to reduce my risk of stroke?

Other than medications, there are a number of ways you can reduce your risk of stroke. These include reducing lifestyle risk factors for stroke.





If you're a smoker, quit smoking – smoking is a major risk factor for stroke.



Reduce your intake of saturated fat and eat plenty of fresh fruits and vegetables – high cholesterol can increase your risk of stroke.



Exercise for 45 minutes daily – this will help improve your overall health and reduce your risk of stroke.



Enjoy alcohol in moderation – excessive drinking can increase your risk of stroke.

Current guidelines recommend no more than two standard drinks on any day for men and women.*

Adapted from: National Stroke Foundation. Understand and prevent stroke. Available at: <https://strokefoundation.com.au/About-Stroke/Preventing-stroke>. Accessed June 2016.

*Source: Australian Government, Department of Health. Standard Alcohol Guidelines. Available at <http://www.alcohol.gov.au>. Accessed June 2016.



Have any questions about your personal risk factors?

Ask your doctor at your next appointment about what lifestyle changes you could make to reduce your risk of stroke.

Questions you may want to ask your doctor

- What are the risks and benefits of anticoagulants?
- Can my anticoagulation medicine be reversed in an emergency?
- What are common side effects of my medication?
- Are there any dietary restrictions that I should follow now?
- Are there any monitoring requirements (e.g. regular blood tests) for my medication?

Take note of any other questions you may have for your doctor in the space below. Take this booklet to your next doctor's appointment so you remember to ask.







YOUR GUIDE TO TAKING PRADAXA

What is Pradaxa?

Pradaxa contains an active ingredient called dabigatran. It belongs to a group of medicines called “anticoagulants”.

Anticoagulants, or anticlotting medicines, are used to help prevent blood clots from forming as a result of non-valvular atrial fibrillation. These clots may be harmful as they can travel in your bloodstream to your brain and cause stroke.

You need to take your Pradaxa each day to help prevent stroke.

Pradaxa is a prescription medicine – it can only be purchased from a pharmacy with a prescription.

What is Pradaxa used for?

There are a number of conditions that can result in an increased risk of blood clots forming. Pradaxa can be used for some of these, such as preventing blood clots in:



A condition called non-valvular atrial fibrillation (NVAF), where the heart beats irregularly.



People recovering from hip or knee surgery.



People who have an increased risk of blood clots forming in their legs (sometimes called deep vein thrombosis or DVT).



Ask your doctor if you have any questions about why this medicine has been prescribed for you.

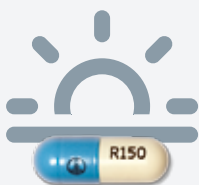
How do I take Pradaxa?

Pradaxa comes in packs of 60 capsules and in two dose strengths:

- A 150 mg capsule; or
- A 110 mg capsule.

Your doctor will determine which dose is appropriate for you. You will most likely be told to take one capsule, twice a day.

Either

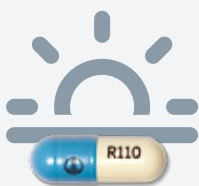


One 150 mg capsule
in the morning.



One 150 mg capsule
in the evening.

OR



One 110 mg capsule
in the morning.



One 110 mg capsule
in the evening.

Capsules are not actual size.

Pradaxa capsules must be swallowed whole with a full glass of water – **do not chew or open the capsule.**

Pradaxa can be taken with or without food.

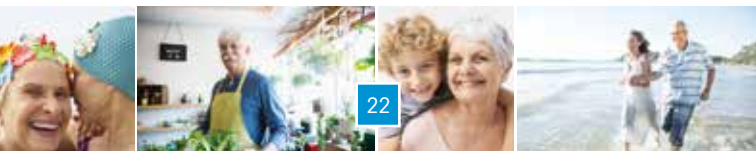


Follow the instructions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this booklet.

How long do I take Pradaxa for?

Continue taking your medicine for as long as your doctor tells you.

Your doctor will continue to prescribe Pradaxa for you as long as it is deemed necessary based on your risk of a blood clot forming.

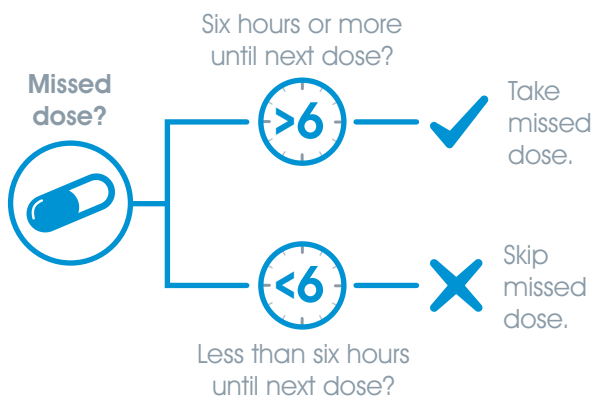


What should I do if I miss a dose?

If you forget to take your dose of Pradaxa, you can still take your missed dose, so long as it is at least six hours before your next dose is due.

A missed dose should not be taken if it is less than six hours before your next dose.

Do not take a double dose to make up for missed doses.



What should I do if I take too much Pradaxa?

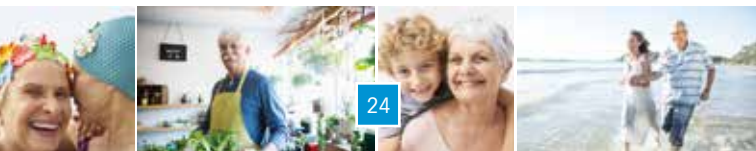
If you think that you or anyone else may have taken too much Pradaxa (overdose), immediately telephone your doctor or the Poisons Information Centre (Australia 13 11 26) for advice, or go to Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. If you take too much Pradaxa you may have bleeding. Blood may be seen in stools or urine. Abnormal bruising may also be experienced.

What if I require surgery?

Your Pradaxa treatment may need to be stopped temporarily prior to having surgery due to an increased risk of bleeding. If you require surgery (including dental surgery), make sure you tell your surgeon and/or dentist you are taking Pradaxa.

Your doctor will advise you when to stop taking Pradaxa and when you can start taking it again after your surgery.



What happens if I require urgent surgery?

If you require urgent surgery, staff at the hospital may be able to give you an injection that will stop the effects of Pradaxa.

Therefore, if you are admitted to hospital for emergency treatment following an injury or if you are admitted for urgent surgery, it is important to tell staff that you are taking Pradaxa.

Your doctor will advise you when you can start taking Pradaxa again after your surgery.



Your Pradaxa Alert Card can be found in the front of this booklet. Carry this card with you at all times. This will tell ambulance officers and emergency care physicians that you're taking Pradaxa.



Pradaxa and bleeding

The main side effect of any anticoagulant, including Pradaxa, is bleeding.

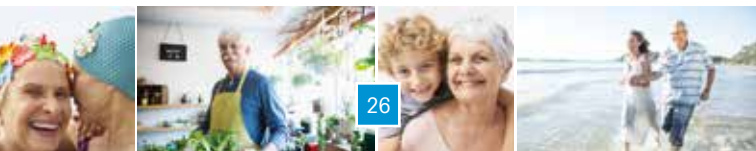
Your doctor will (in consultation with you) prescribe you the most appropriate dose of Pradaxa to help balance the benefits of preventing clots from forming and the risk of bleeding occurring.

You can help keep yourself well by watching out for signs of bleeding – if they are detected early, you can prevent small problems from becoming serious.

For more information on the signs of bleeding, please see the “Signs of bleeding” section on page 12.



If any of these signs of bleeding occur, you should contact your doctor immediately. If your doctor is not available, go to your nearest hospital emergency department.



What other side effects are associated with Pradaxa?

Pradaxa is generally well tolerated. A common side effect is heartburn or indigestion, especially if taken on an empty stomach. This can usually be avoided if Pradaxa is taken with a full glass of water or after food.



It is important that you do not stop taking Pradaxa without talking to your doctor or pharmacist.



Frequently asked questions (FAQs) about taking Pradaxa

Here are some answers to questions commonly asked about taking Pradaxa. These may help make sure your treatment is as simple and convenient as possible, but do not replace the advice of your doctor.



Do I need regular blood tests while taking Pradaxa?

Your doctor may request occasional blood tests related to your Pradaxa treatment, but you do not need to have regular blood tests to monitor if Pradaxa is working properly.



Can I take other medications with Pradaxa?

Some medicines and Pradaxa may interfere with each other. Always tell your doctor or pharmacist about other medications you are taking (including any that you get without a prescription from your pharmacy, supermarket or health food shop).



Can I still take aspirin while I'm on Pradaxa?

Some people take a small daily dose of aspirin. Taking aspirin with Pradaxa may increase your risk of bleeding. If you are already taking aspirin, check with your doctor to find out if you need to keep taking it while you are taking Pradaxa. Always ask your doctor before taking aspirin while taking Pradaxa.



Can I take complementary medicines while I'm on Pradaxa?

Generally, complementary medicines, including herbal medicines, can be taken with Pradaxa but make sure your treating doctor and pharmacist are aware that you are taking them. Some complementary medicines can have a blood-thinning effect so it is important that you inform your doctor and pharmacist if you are taking any complementary medicines. St John's Wort can significantly decrease the effect of Pradaxa, so discuss with your doctor if you are taking, or plan to take St John's Wort.



How do I store Pradaxa?

Pradaxa should be stored in a cool, dry place below 30°C. Keep the capsules in the original packaging until the dose is due.



Can I still drink alcohol while taking Pradaxa?

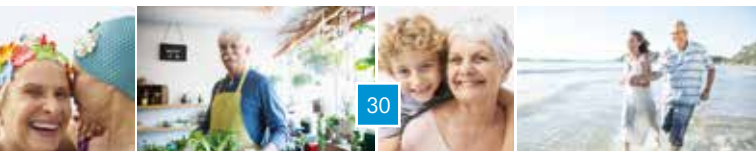
Consuming large amounts of alcohol, especially binge drinking, can increase the risk of bleeding. It is best to limit your daily intake to no more than one or two standard drinks a day, with at least two alcohol free days a week.* Some people may have other medical reasons for avoiding alcohol completely. Discuss with your doctor or pharmacist the alcohol intake that is safe for you.

*Australian Government, Department of Health. Standard Alcohol Guidelines. Available at: <http://www.alcohol.gov.au>. Accessed June 2016.



Will I have to change my diet while taking Pradaxa?

No. As the effect of Pradaxa is not altered by different foods or drinks, you do not need to make any changes to your diet when taking Pradaxa.





What about pregnancy and breastfeeding?

Pradaxa should not be taken if you are pregnant, considering becoming pregnant or are breastfeeding.



What about travelling while I'm on Pradaxa?

Whilst Pradaxa does not require regular blood tests or dietary restrictions, when you are travelling, you should take the following measures:

- Make sure you take enough Pradaxa capsules with you to last the entire trip;
- Keep the capsules in their original packaging and store your Pradaxa in a cool dry place below 30°C; and
- If you consult a doctor while you are away, inform them you are taking Pradaxa.





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