

Pradaxa[®]

[dabigatran etexilate]

patient support booklet

Important information
about your medication
and how to take it to help
you reduce your **risk of
stroke** associated with
atrial fibrillation



You have been given
Pradaxa[®] to help
reduce your risk of
having a stroke due
to atrial fibrillation.

Please read this leaflet
carefully, together with
the information leaflet
inside your box of
Pradaxa[®] capsules.

If anything is unclear,
please ask your doctor,
nurse or pharmacist.

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What is Pradaxa®?

Pradaxa® is a medicine used to reduce the risk of a person with atrial fibrillation [AF] having a stroke.

A stroke is a serious, sometimes life-threatening condition that occurs when the blood supply to part of the brain is restricted or cut off.

Strokes in AF are caused by a blood clot. A blood clot is a thickened lump of blood that can block blood vessels, such as those carrying blood to the brain. Pradaxa® works by stopping blood clots from forming.

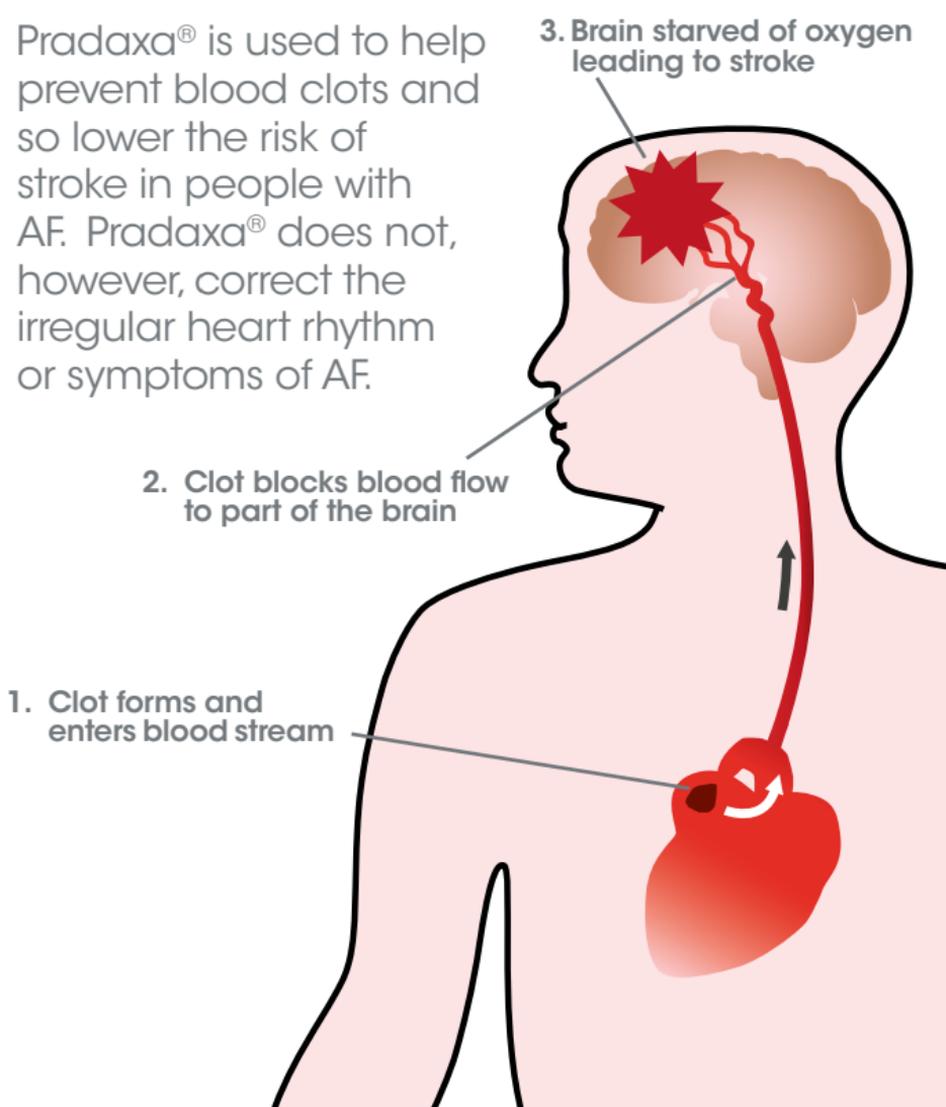
Why have I been prescribed Pradaxa®?

Your doctor has prescribed Pradaxa® as part of the management of your AF.

AF is a heart condition that causes an irregular and often unusually fast heart rate, but some patients may not always notice symptoms.

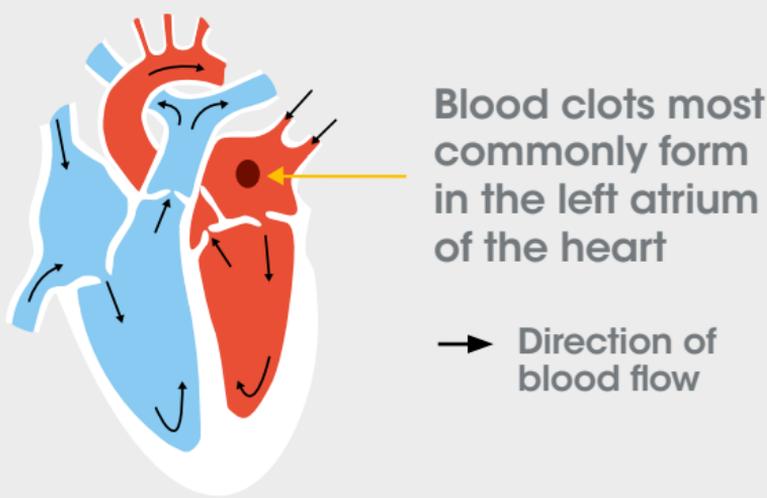
Blood clots can form in the heart as a result of AF. These clots can then be pumped into the general circulation. Blood clots in the general circulation can block blood vessels in the brain, causing a stroke.

Pradaxa® is used to help prevent blood clots and so lower the risk of stroke in people with AF. Pradaxa® does not, however, correct the irregular heart rhythm or symptoms of AF.



How does Pradaxa[®] work?

Pradaxa[®] is a type of medicine called an anticoagulant and is designed to reduce the chance of blood clots forming. It does this by working to stop blood cells from clumping together.



Anticoagulants are sometimes called 'blood thinners', but they don't actually thin the blood at all.

An anticoagulant simply slows down the blood's clotting process, making it less likely to clot.

So if you cut yourself while on Pradaxa[®], you will bleed for longer, but the bleeding will stop.

How do I take Pradaxa[®]?



Take one Pradaxa[®] capsule in the morning and one in the evening [i.e. one capsule twice a day].

It's important to take Pradaxa[®] at roughly the same times each day, for example at 8am and 8pm.

The Pradaxa[®] blister case can help you keep track of how many capsules you have taken and still need to take [see next page].



Pradaxa[®] should be swallowed whole with a glass of water. Taking with food may help reduce the possibility of indigestion.



Never bite into a Pradaxa[®] capsule; always swallow it whole

Storing Pradaxa®



Store your Pradaxa® capsules at room temperature and always within the foil packaging that they came in.



Only break the foil and remove a capsule when you are ready to take it, so that it is not affected by moisture in the air.



The Pradaxa® blister case can be used to store your medication whilst keeping it inside the foil packaging. It also provides a handy reminder of how many capsules you have taken and how many you still need to take.

How long do I take Pradaxa[®] for?

Keep taking Pradaxa[®] exactly as prescribed, unless your doctor tells you to stop.

You may need to take Pradaxa[®] for the rest of your life, so it's good to get into a routine, e.g. taking one capsule with breakfast and another with dinner.



What if I miss a dose of Pradaxa[®]?

If you forget to take a Pradaxa[®] capsule, work out how much time there is until your next dose is due:



- If it's more than 6 hours until your next Pradaxa[®] capsule is due to be taken, take the Pradaxa[®] capsule that you have missed straight away



- If your next Pradaxa[®] capsule is due to be taken in less than 6 hours time, do not take the dose that you have missed. Wait until your next dose is due, then take your Pradaxa[®] capsule and carry on as usual



Never take

a double dose of Pradaxa[®] to make up for a missed dose

What if I accidentally take an extra dose of Pradaxa®?

If you take an extra dose of Pradaxa® by mistake, contact your doctor or anticoagulation clinic **as soon as possible**.

This is very important, as your doctor may wish to do a blood test to assess your risk of bleeding.



Does Pradaxa® have side effects?

As with all medicines, Pradaxa® may cause side effects in some people. Because of the way Pradaxa® works, most of these side effects are related to bleeding and bruising. The more common side effects with Pradaxa® are:

- Nosebleeds
- Bleeding into the stomach or bowel
- Stomach ache
- Frequent loose or liquid bowel movements
- Indigestion
- Feeling sick

Very rarely more severe bleeding may occur. If you suffer from excessive bleeding, excessive tiredness, weakness, dizziness or unexplained swelling, you should speak to your doctor immediately and they will decide what action needs to be taken.

Full details of possible side effects can be found in the information leaflet inside your box of Pradaxa® capsules.



When should I seek medical help?

Seek medical help immediately if you experience any of the following:

- ❗ Vomiting blood
- ❗ Blood in your urine [making it red or brown]
- ❗ Blood in your stools (poo) [they may look red or black]
- ❗ A nosebleed that lasts for longer than 10 minutes despite applying pressure
- ❗ Excessive tiredness, weakness, dizziness or unexplained swelling
- ❗ A fall or injury [especially if you hit your head]
- ❗ Any excessive bleeding

What can be done to stop the effect of Pradaxa® in an emergency?

In case of an emergency, the blood thinning effect of Pradaxa® can be immediately switched off by a medicine called Praxbind® (idarucizumab). Praxbind® can be given to you in hospital through your vein and works by quickly trapping the Pradaxa® in your blood and de-activating it. Praxbind® can be given by a doctor in emergency situations, for example, if you are taking Pradaxa® and need an urgent operation for any reason, or if you have serious bleeding that will not stop.

Remember...

Contact your doctor a few days before you are going to run out of Pradaxa[®], so that they can give you another prescription.



Make sure that you carry your patient alert card with you at all times whilst taking Pradaxa[®]. If you see a doctor or dentist whilst taking Pradaxa[®] please show them the card which you will find contained in your box of medication.



When you see a doctor, surgeon, dentist or pharmacist for the first time, always tell them that you are taking Pradaxa[®].



If you get any side effects after taking Pradaxa[®] or being given Praxbind[®], talk to your doctor, pharmacist or nurse. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard (UK) or HPRAs Pharmacovigilance Website at www.hpra.ie (Ireland). By reporting side effects you can help provide more information on the safety of these medicines.

Further information

Please read the leaflet that comes inside your box of Pradaxa[®] capsules.

The Patient Information Leaflets and Summary of Product Characteristics for Pradaxa[®] can be found online by visiting www.medicines.org.uk/emc (UK) or www.medicines.ie (Ireland) and searching for 'Pradaxa'.

For more information about AF or anticoagulation you can visit or contact one of the following sources:

Atrial Fibrillation Association

www.heartrhythmalliance.org/afa/uk
01789 867 502
info@afa.org.uk

Anticoagulation UK

www.anticoagulationuk.org
info@anticoagulationuk.org

Stroke Association

www.stroke.org.uk

NHS Choices

www.nhs.uk/Conditions/Atrial-fibrillation

If you have any feedback on this piece of information please contact:
medinfo.bra@boehringer-ingelheim.com

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