

Dabigatran (Pradaxa) for preventing blood clots after hip or knee replacement surgery

This *Medicine Update* is for people who have been prescribed dabigatran.

Summary

Dabigatran is a new medicine to prevent blood clots forming after hip or knee replacement surgery. It works by thinning the blood.

Dabigatran is available as capsules that you swallow. It is important that you take dabigatran every day for the prescribed number of days.

Dabigatran appears to be as safe and effective as other blood thinning medicines but, as with these other medicines, you need to be aware of the signs of bleeding.

www.nps.org.au/medicineupdate



National Prescribing Service Limited

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get to know your medicines

Contents

	Section
What dabigatran is.....	1
What dabigatran is for	2
Who can take dabigatran.....	3
When to take dabigatran.....	4
How to take dabigatran	5
Important side effects to consider.....	6
What else you should know about dabigatran.....	7
Other medicines available.....	8
What does dabigatran cost?.....	9
Other ways to prevent blood clots	10
Where to find more information.....	Back page

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 starting, or thinking of starting, a particular medicine. It is also for their carers.

Where does *Medicine Update* come from?

Medicine Update is written by the National Prescribing Service Limited (NPS) in consultation with consumers and health professionals. NPS is an independent, non-profit, government-funded organisation.

NPS takes reasonable care to ensure this information is accurate and up-to-date at the time of creation. It is for your information only and is not medical advice. NPS does not warrant its completeness and excludes liability where permitted by law. We recommend you seek advice from a health professional about your medical condition.

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

Dabigatran is used to prevent blood clots forming in the leg veins after hip or knee replacement surgery. The medical term for these blood clots is deep vein thrombosis (DVT).

A blood clot in the legs can travel through the bloodstream to the lungs, where it can block an artery. This is a serious condition known as a pulmonary embolism. It may be life threatening.

3. Who can take dabigatran

People can be prescribed dabigatran through the Pharmaceutical Benefits Scheme (PBS) to prevent blood clots forming after hip or knee replacement surgery.

You may be given another medicine instead to prevent blood clots (see Section 8: Other medicines available).

4. When to take dabigatran

You will usually be given this medicine 1 to 4 hours after surgery. You will need to continue taking it every day for the prescribed number of days.

Dabigatran must be taken each day at about the same time for:

- 28 to 35 days following a hip replacement
- 10 days following a knee replacement.

You may be given enough dabigatran capsules to complete your course of treatment when you leave hospital.

Other hospitals will give you only a small supply of dabigatran capsules and you will need to either:

- visit your GP to get a prescription to complete your course, or
- visit your local pharmacist to fill the dabigatran prescription given to you in hospital.

Finish the dabigatran capsules from the hospital before you start taking the capsules from your GP or pharmacist.

Make sure you tell your GP or pharmacist the date of your surgery and ask them the date when you should stop taking the capsules.

Write this date on the box and do not take any dabigatran capsules after this date.

It is important that you have enough dabigatran capsules to complete your course of treatment.

It is important that you do not accidentally take dabigatran capsules from the hospital and dabigatran capsules you get from your GP or pharmacist at the same time.

5. How to take dabigatran

Always take dabigatran exactly as prescribed.

The first dose is a single capsule that is usually given 1 to 4 hours after surgery.

After that, the daily dose is two capsules taken together. Each capsule contains 110 milligrams of medicine, so the total dose is 220 milligrams.

If you have kidney problems, or are taking other medicines that thin your blood, your doctor will prescribe a lower dose of 150 milligrams (two capsules of 75 milligrams).

You should take your daily dose at about the same time each day. Swallow the two capsules whole with water. They can be taken with or without food.

If you forget to take your dabigatran capsules, do not take a double dose the next day because this will increase the risk of bleeding.

6. Important side effects to consider

All medicines can have side effects. Sometimes the side effects are serious, but most of the time they are not.

For dabigatran and other blood thinning medicines, the main risk is bleeding.

You may find that some blood seeps through the dressing after your operation. Some seepage is normal, but if you think that the bleeding is excessive speak to your doctor about it.

You should seek urgent medical attention if you have:

- bleeding that won't stop
- nosebleeds that last for longer than 10 minutes
- unexplained or severe bruising.

Internal bleeding is harder to detect, but can be very serious. If you experience any of the following, contact your doctor immediately or go to the emergency department at your nearest hospital:

- blood in your urine
- red or black faeces
- 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.

Dabigatran has been tested in clinical trials, but it is a new medicine so the full range of side effects is not known. You should be aware of this and see your doctor straight away if you have any concerns.

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

Ask your doctor about the possible side effects of this medicine before you use it.

Always tell your doctor about any changes to your condition if you are taking a new medicine.

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

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.

7. What else you should know about dabigatran

If you stop taking dabigatran too early you are at greater risk of developing a blood clot in the veins of your leg. Make sure that you take it for the number of days that your doctor, pharmacist or nurse has told you.

While you are taking dabigatran, you should talk to your doctor before taking other medicines that can increase your risk of bleeding. These include:

- aspirin
- medicines that reduce pain and inflammation like:
 - ibuprofen (Advil, Brufen, Nurofen, Rafen)
 - diclofenac (Fenac, Voltaren)
 - naproxen (Naprogesic, Naproleve, Naprosyn, Proxen).

If you have a mild headache or other pain, or fever associated with a cold, you may use paracetamol (Panadol, Panamax).

Your hospital doctor will consider any other health problems you might have before prescribing dabigatran for you.

Dabigatran may **not** be suitable for you if you have:

- severely reduced kidney function
- severe liver disease
- had a stroke in the previous 6 months
- very high blood pressure
- a medical condition that increases your risk of bleeding.

Some other medicines can interact with dabigatran. You should talk to your doctor before taking any other medicine from a pharmacy, supermarket or health food store.

8. Other medicines available

Some medicines to prevent blood clots after hip or knee replacement surgery are given as a daily injection. They include dalteparin (Fragmin), enoxaparin (Clexane) and fondaparinux (Arixtra).

Dabigatran is a new blood thinning (anticoagulant) medicine available in capsule form. Another new anticoagulant — called rivaroxaban (Xarelto) — is available in tablet form. These two medicines work in slightly different ways, but in clinical trials both were found to be about as effective as a daily injection of enoxaparin. The risk of bleeding was also similar.

Remember that risks and benefits differ between medicines and from person to person.

9. What does dabigatran cost?

The full cost of dabigatran to the Australian Government varies depending on the strength of the capsules and the size of the pack.

The costs are as follows:

- \$81.16 for 75 mg dabigatran capsules (pack size 20 capsules)
- \$228.21 for 75 mg dabigatran capsules (pack size 60 capsules)
- \$81.16 for 110 mg dabigatran capsules (pack size 20 capsules)
- \$228.21 for 110 mg dabigatran capsules (pack size 60 capsules).

If you get dabigatran through the Pharmaceutical Benefits Scheme (PBS), the Australian Government pays most of the cost and you will pay only a part, called the co-payment.

At the time of publication, the co-payment for people who are entitled to get dabigatran through the PBS was:

- \$33.30 for people without a concession card
- \$5.40 for concession card holders.

If you are not eligible to get dabigatran through the PBS, you will need to pay the full price for a prescription.

Most medicines prescribed by your doctor are covered by the 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 pbs.gov.au.

10. Other ways to prevent blood clots



In addition to taking an anticoagulant medicine such as dabigatran, you should wear compression stockings while you are recovering from hip or knee replacement surgery. These further reduce your risk of blood clots.

You will also be given a program of exercises to help with your recovery.

Where to find out more information

To find out more about dabigatran

Call Medicines Line on 1300 888 763 to speak to a pharmacist (Mon–Fri, 9am–5pm EST for the cost of a local call, mobile calls more).

Read the consumer medicine information (CMI) leaflet for this medicine. The CMI will tell you:

- who should not take the medicine
- which medicines should not be taken at the same time (medicine interactions)
- how to take the medicine
- most of the possible side effects
- the ingredients.

You can get the CMI leaflet for Pradaxa (dabigatran) from:

- your doctor or pharmacist
- CMI search on the NPS website
- Boehringer Ingelheim, the makers of Pradaxa (dabigatran), on 1800 226 315.

To report a side effect with dabigatran

Call the Adverse Medicines Event (AME) Line on 1300 134 237 (Mon–Fri, 9am–5pm EST).

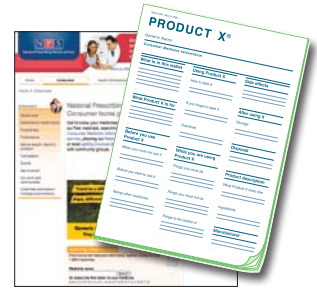
The AME Line lets you report and discuss side effects that might be related to your medicine. The side effects of your medicine — but not your personal details — are reported to the Australian medicines regulatory agency (the Therapeutic Goods Administration or TGA for short). The information helps to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

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

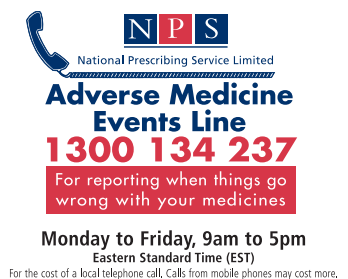
More about taking medicines

For more information on how new medicines are tested and approved in Australia see the NPS factsheet *New medicines: are they always better?* at www.nps.org.au/consumers/publications/factsheets

More information on understanding side effects is available from www.asmi.com.au



Visit the NPS website to find out about our free activities and resources for consumers:
www.nps.org.au/consumers



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