

New Zealand Consumer Medicine Information

PRADAXA[®]

Capsules

Dabigatran etexilate

What is in this leaflet

This leaflet answers some common questions about PRADAXA. It does not contain all available information, nor does it take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the expected benefits.

Keep this information with your capsules. You may need to read it again later.

To find out more about PRADAXA

You should ask your doctor or pharmacist if you have any questions about your medicine or if you have any trouble before, during or after using PRADAXA.

What PRADAXA is used for

PRADAXA contains an active ingredient called dabigatran etexilate (as dabigatran etexilate mesilate). After oral use, dabigatran etexilate is rapidly converted in the body to its active form dabigatran. Dabigatran inhibits a specific protein in the blood, called thrombin. Thrombin contributes to the formation of blood clots. Dabigatran prevents the formation of blood clots.

This type of medication is called an anticoagulant. Some people refer to anticoagulant medicines as “blood thinners”. Excessive clotting sometimes occurs when physical mobility is low such as following major orthopaedic surgery of the lower limb and due to a heart condition called atrial fibrillation in which the heart beats irregularly.

If excessive clotting is not prevented, it can lead to serious health problems such as strokes.

Before you take PRADAXA

When you must not take it

Do not take PRADAXA if you have:

- severely reduced kidney function. Your doctor will know how to determine your kidney function
- an increased tendency of bleeding complications, be it inherited, acquired or caused by other medicines
- medical conditions which increase your risk of bleeding, including brain bleeding within the last 6 months
- a history of bleeding in the head, eyes, spine and joints

- active stomach ulcers or stomach bleeding in the past year, unless it has been fixed
- liver problems or liver disease

Do not take PRADAXA if you are currently taking oral ketoconazole, a medicine used to treat fungal infections.

Do not start PRADAXA and verapamil treatment at the same time. Do not start verapamil if you are currently taking PRADAXA and have just undergone major orthopaedic surgery.

Do not take PRADAXA if you are allergic to dabigatran etexilate or any of the ingredients. These ingredients are listed in full at the end of this leaflet (see ingredients). PRADAXA contains sunset yellow FCF C115985, which may cause allergic reactions. Some of the symptoms of an allergic reaction may include:

- rash, itching or hives on the skin
- swelling of the face, lips, tongue or other parts of the body
- shortness of breath, wheezing or troubled breathing.

Do not take it after the expiry date (EXP) printed on the pack. If you take it after the expiry date has passed, it may not work as well. Do not take it if the packaging is torn or shows signs of tampering.

Before you start to take it

You must tell your doctor or pharmacist if:

1. you have allergies to any other medicines including aspirin or other NSAID (anti-inflammatory) medicines or any other substances such as foods, preservatives or dyes.
2. you are pregnant or intend to become pregnant. Like most medicines of this kind, PRADAXA is not recommended to be used during pregnancy. Your doctor will discuss the risks and benefits of using it if you are pregnant.
3. you are breastfeeding or intend to breast feed.
4. you have or have had any medical conditions, especially the following:
 - reduced liver function, life-threatening liver disease or increased liver enzymes.
 - increased bleeding risk. For example: blood clotting disorders, gastrointestinal bleeding, recent tissue sampling (biopsy), recent brain bleed, recent brain, spinal or eye surgery, or an inflammation of parts of your heart (endocarditis).
 - severely reduced kidney function.

Do not give PRADAXA to a child or adolescent. There is no experience with its use in children or adolescents under 18 years old.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking PRADAXA.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or

health food shop. There may be interference between PRADAXA and some medicines. These include:

- aspirin, salicylates or other NSAID (anti-inflammatory) medicines
- medicines used to thin your blood (such as warfarin, unfractionated heparins, heparin derivatives, low molecular weight heparins, fondaparinux, desirudin, clopidogrel, tirofiban, bivalirudin, prasugrel, ticagrelor eptifibatide, ticlopidine, dextran, sulfinpyrazone and rivaroxaban)
- amiodarone, dronedarone, quinidine, medicines used to treat irregular heartbeats
- verapamil, a calcium channel blocker used to treat high blood pressure and angina
- clarithromycin or rifampicin, medicines used to treat infections
- lopinavir, nelfinavir, ritonavir, tipranavir or saquinavir, medicines used to treat HIV infections
- cyclosporin or tacrolimus, medicines used to help the body's immune system
- herbal medicines derived from St John's wort (*Hypericum perforatum*).
- carbamazepine, a medicine used to treat fits or convulsions.

These medicines may be affected by PRADAXA or may affect how well it works. You may need to use different amounts of your medicines, change the timing of your medicine-taking routine or take different medicines. Your doctor or pharmacist will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking PRADAXA.

Taking PRADAXA

How to take PRADAXA

Blisters

To remove PRADAXA capsules from the blister pack:

- Peel off the backing foil of the blister card
- Do not push the PRADAXA capsules through the blister foil
- Do not peel off the blister foil until a PRADAXA capsule is required.

Bottle

To remove PRADAXA capsules out of the bottle:

- Push and turn for opening

Swallow the capsules whole with a full glass of water. Do not chew or open the capsule. Do not sprinkle the pellets on food or mix with liquids.

Take PRADAXA at about the same time each day. Taking your capsules at the same time each day will have the best effect. It will also help you remember to take the capsules. It does not matter if you take this medicine with or without food, however if you experience dyspepsia (heartburn) you may find it helps to take PRADAXA with food.

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

If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.

How much to take

After knee and hip replacement surgery

The recommended dose of PRADAXA is 220 mg (2 capsules of 110 mg) taken as a single dose once daily.

Patients with moderately reduced kidney function (e.g. over 75 years) or patients taking certain medicines may have an increased risk of bleeding. The doctor may prescribe the lower dose of 150 mg once daily, taken as 2 capsules of PRADAXA 75 mg.

After knee replacement surgery:

Treatment with PRADAXA should be started within 1 – 4 hours of completed surgery, using a single capsule of 110 mg and continuing with 2 capsules of 110 mg once daily for a total of 10 days.

After hip replacement surgery:

Treatment with PRADAXA should be started within 1- 4 hours of completed surgery, using a single capsule of 110 mg and continuing with 2 capsules of 110 mg once daily for a total of 28 – 35 days.

If, within 4 hours after surgery, post-operative bleedings can still be observed, initiation of treatment should be delayed. If treatment is not started on the day of surgery then treatment should be initiated with 2 capsules of 110 mg once daily.

Follow the initiation instructions given to you by your doctor carefully.

For stroke prevention in patients with atrial fibrillation

The recommended dose of PRADAXA is 300 mg taken as 1 capsule of 150 mg in the morning and 1 capsule of 150 mg in the evening.

Patients over 80 years should take a lower dose of 220 mg, taken as 1 capsule of 110 mg in the morning and 1 capsule of 110 mg in the evening.

Patients with an increased risk of major bleeding (as determined by your doctor) should take a lower dose of 220 mg, taken as 1 capsule of 110 mg in the morning and 1 capsule of 110 mg in the evening.

How long to take it

After knee replacement surgery

Continue taking your medicine for as long as your doctor tells you. This will usually be for a period of 10 days.

After hip replacement surgery

Continue taking your medicine for as long as your doctor tells you. This will usually be for a period of 28 – 35 days.

It is important to keep taking your medicine even if you feel well.

If you stop using PRADAXA before your doctor tells you to stop, you are at risk of developing a blood clot in a vein of your leg which can move to the lungs and be life-threatening.

Tell your doctor immediately or go to casualty at your nearest hospital if you notice swelling of the leg or cough and shortness of breath.

These could be signs of a blood clot.

Tell your doctor if you intend stopping treatment earlier.

For stroke prevention in patients with atrial fibrillation:

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

It is important to keep taking your medicine even if you feel well.

If you stop using PRADAXA before your doctor tells you to stop, you are at risk of developing a blood clot. This can lead to serious health problems such as strokes. PRADAXA will continue to be prescribed while there is a risk of excessive clotting.

If you forget to take it

After knee and hip replacement surgery continue with your remaining daily doses of PRADAXA at the same time of the next day.

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

For stroke prevention in patients with atrial fibrillation a forgotten dabigatran etexilate dose may still be taken up to 6 hours prior to the next scheduled dose.

From 6 hours prior to the next scheduled dose on, the missed dose should be omitted. Do not take a double dose to make up for missed individual doses.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for hints.

If you have taken too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (phone 0800 764 766) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much PRADAXA. Do this even if there are no signs of discomfort or poisoning.

Possible signs of taking too many PRADAXA capsules include bleeding. Blood may be seen in stools or urine. Abnormal bruising may also be experienced.

While you are taking PRADAXA

Things you must do

Tell all doctors and pharmacists who are treating you that you are taking PRADAXA.

Tell your doctor if, for any reason, you have not used PRADAXA exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

If you become pregnant while using PRADAXA, tell your doctor immediately.

If you are going to have surgery, including dental surgery, tell your doctor or dentist that you are taking PRADAXA. PRADAXA should be temporarily stopped before surgery.

Your doctor will tell you when to stop using PRADAXA before your surgery.

Your doctor will tell you when to re-start using PRADAXA after your surgery.

Things you must not do

Do not give the capsules to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

No studies on the effects of PRADAXA on the ability to drive and operate machinery have been performed. Driving or operating machinery should be avoided for a period of time after orthopaedic surgery.

Side effects

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PRADAXA.

Tell your doctor as soon as possible if you notice any of the following and they worry you:

- bruising
- nosebleeds
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale (signs of anaemia).
- diarrhoea
- indigestion
- cough
- painful, swollen joints
- sore nasal passages and throat discomfort when swallowing.

These side effects are usually mild.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- chest pain or being short of breath
- swelling of hands, ankles and feet
- bleeding
- red or dark brown urine
- red or black bowel motions.

These are serious side effects. You may need urgent medical attention.

Other side effects not listed above may occur in some people.

Tell your doctor if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking PRADAXA

Storage

Keep your capsules in the blister pack or bottle until it is time to take them. If you take them out of the blister pack or bottle they may not keep well.

Once the bottle is opened, the capsules must be used within 4 months. Keep the bottle tightly closed.

Keep PRADAXA in a cool dry place where the temperature stays below 30 degrees C. Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill. Do not leave it in the car. Heat and damp can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking the capsules, or the capsules have passed their expiry date, ask your pharmacist what to do with any that are left over. Return any unused medicine to your pharmacist.

Product Description

What it looks like

PRADAXA comes in two types of capsules:

- PRADAXA 75 mg - light blue-coloured, opaque cap with a cream-coloured, opaque body, imprinted with a R75 code on one side and company logo on the other.

Available in blister packs of 10 and 60 capsules or bottles of 60 capsules.

- PRADAXA 110 mg - light blue-coloured, opaque cap with a cream-coloured, opaque body, imprinted with a R110 code on one side with company logo on the other.

Available in blister packs of 10 and 60 capsules or bottles of 60 capsules.

- PRADAXA 150 mg – light blue-coloured, opaque cap with a cream-coloured, opaque body imprinted with a R150 code on one side and company logo on the other.

Available in blister packs of 10 and 60 capsules or bottles of 60 capsules.

Not all pack sizes and presentations are available.

Ingredients

Active ingredient:

- PRADAXA 75 mg - 75 mg dabigatran etexilate given as 86.48 mg dabigatran etexilate mesilate per capsule
- PRADAXA 110 mg - 110 mg dabigatran etexilate given as 126.83 mg dabigatran etexilate mesilate per capsule.
- PRADAXA 150 mg – 150 mg dabigatran etexilate given as 172.95 mg dabigatran etexilate mesilate per capsule.

Inactive ingredients:

Capsule fill

- acacia
- dimethicone
- hydroxypropylcellulose
- hypromellose
- talc
- tartaric acid

Capsule shell

- carrageenan
- potassium chloride
- titanium dioxide
- indigo carmine CI73015
- sunset yellow FCF CI5985
- hypromellose
- water - purified

Black printing ink

- shellac
- tert-butyl alcohol
- isopropyl alcohol
- methylated spirit - industrial
- iron oxide black CI77499
- water - purified
- propylene glycol.

PRADAXA does not contain gluten, sucrose or tartrazine.

Manufacturer

PRADAXA capsules are made in Germany and supplied in New Zealand by:

BOEHRINGER INGELHEIM (N.Z.) LIMITED
PO Box 76-216
Manukau City
Auckland
Ph 0800 802461

This leaflet was prepared on 18 November 2011
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