

MEDICATION GUIDE
PRADAXA (pra dax a)
(dabigatran etexilate mesylate)
capsules

Read this Medication Guide before you start taking PRADAXA and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about PRADAXA?

• **For people taking PRADAXA for atrial fibrillation:**

People with atrial fibrillation (a type of irregular heartbeat) are at an increased risk of forming a blood clot in the heart, which can travel to the brain, causing a stroke, or to other parts of the body. PRADAXA lowers your chance of having a stroke by helping to prevent clots from forming. If you stop taking PRADAXA, you may have increased risk of forming a clot in your blood.

Do not stop taking PRADAXA without talking to the doctor who prescribes it for you. Stopping PRADAXA increases your risk of having a stroke.

PRADAXA may need to be stopped, if possible, prior to surgery or a medical or dental procedure. Ask the doctor who prescribed PRADAXA for you when you should stop taking it. Your doctor will tell you when you may start taking PRADAXA again after your surgery or procedure. If you have to stop taking PRADAXA, your doctor may prescribe another medicine to help prevent a blood clot from forming.

- PRADAXA can cause bleeding which can be serious, and sometimes lead to death. This is because PRADAXA is a blood thinner medicine that lowers the chance of blood clots forming in your body.
- **You may have a higher risk of bleeding if you take PRADAXA and:**
 - are over 75 years old
 - have kidney problems
 - have stomach or intestine bleeding that is recent or keeps coming back, or you have a stomach ulcer
 - take other medicines that increase your risk of bleeding, including:
 - aspirin or aspirin containing products
 - long-term (chronic) use of non-steroidal anti-inflammatory drugs (NSAIDs)
 - warfarin sodium (Coumadin[®], Jantoven[®])
 - a medicine that contains heparin
 - clopidogrel bisulfate (Plavix[®])
 - prasugrel (Effient[®])
 - have certain kidney problems and also take the medicines dronedarone (Multaq[®]) or ketoconazole tablets (Nizoral[®]).

Tell your doctor if you take any of these medicines. Ask your doctor or pharmacist if you are not sure if your medicine is one listed above.

- PRADAXA can increase your risk of bleeding because it lessens the ability of your blood to clot. While you take PRADAXA:
 - you may bruise more easily
 - it may take longer for any bleeding to stop

Call your doctor or get medical help right away if you have any of these signs or symptoms of bleeding:

- unexpected bleeding or bleeding that lasts a long time, such as:
 - unusual bleeding from the gums
 - nose bleeds that happen often
 - menstrual bleeding or vaginal bleeding that is heavier than normal
- bleeding that is severe or you cannot control
- pink or brown urine
- red or black stools (looks like tar)
- bruises that happen without a known cause or get larger
- cough up blood or blood clots
- vomit blood or your vomit looks like “coffee grounds”
- unexpected pain, swelling, or joint pain
- headaches, feeling dizzy or weak

Take PRADAXA exactly as prescribed. Do not stop taking PRADAXA without first talking to the doctor who prescribes it for you. Stopping PRADAXA may increase your risk of a stroke.

PRADAXA may need to be stopped, if possible, for one or more days before any surgery, or medical or dental procedure. If you need to stop taking PRADAXA for **any reason**, talk to the doctor who prescribed PRADAXA for you to find out when you should stop taking it. Your doctor will tell you when to start taking PRADAXA again after your surgery or procedure.

Spinal or epidural blood clots (hematoma). People who take a blood thinner medicine (anticoagulant) like PRADAXA, and have medicine injected into their spinal and epidural area, or have a spinal puncture have a risk of forming a blood clot that can cause long-term or permanent loss of the ability to move (paralysis). Your risk of developing a spinal or epidural blood clot is higher if:

- a thin tube called an epidural catheter is placed in your back to give you certain medicine.
- you take NSAIDs or a medicine to prevent blood from clotting
- you have a history of difficult or repeated epidural or spinal punctures
- you have a history of problems with your spine or have had surgery on your spine.

If you take PRADAXA and receive spinal anesthesia or have a spinal puncture, your doctor should watch you closely for symptoms of spinal or epidural blood clots. Tell your doctor right away if you have back pain, tingling, numbness, muscle weakness (especially in your legs and feet), loss of control of the bowels or bladder (incontinence).

See “What are the possible side effects of PRADAXA?” for more information about side effects.

What is PRADAXA?

PRADAXA is a prescription blood thinner medicine that lowers the chance of blood clots forming in your body. PRADAXA is used to:

- reduce the risk of stroke and blood clots in people who have a medical condition called atrial fibrillation. With atrial fibrillation, part of the heart does not beat the way it should. This can lead to blood clots forming and increase your risk of a stroke.
- treat blood clots in the veins of your legs (deep vein thrombosis) or lungs (pulmonary embolism) and reduce the risk of them occurring again.

PRADAXA is not for use in people with artificial (prosthetic) heart valves.

It is not known if PRADAXA is safe and works in children.

Who should not take PRADAXA?

Do not take PRADAXA if you:

- currently have certain types of abnormal bleeding. Talk to your doctor before taking PRADAXA if you currently have unusual bleeding.
- have had a serious allergic reaction to PRADAXA. Ask your doctor if you are not sure.
- have ever had or plan to have a valve in your heart replaced

What should I tell my doctor before taking PRADAXA?

Before you take PRADAXA, tell your doctor if you:

- have kidney problems
- have ever had bleeding problems
- have ever had stomach ulcers
- have any other medical condition
- are pregnant or plan to become pregnant. It is not known if PRADAXA will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if PRADAXA passes into your breast milk.

Tell all of your doctors and dentists that you are taking PRADAXA. They should talk to the doctor who prescribed PRADAXA for you, before you have **any** surgery, or medical or dental procedure.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Some of your other medicines may affect the way PRADAXA works. Certain medicines may increase your risk of bleeding. See **“What is the most important information I should know about PRADAXA?”**

Especially tell your doctor if you take:

- rifampin (Rifater[®], Rifamate[®], Rimactane[®], Rifadin[®])

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

How should I take PRADAXA?

- Your doctor will decide how long you should take PRADAXA. **Do not stop taking PRADAXA without first talking with your doctor. Stopping PRADAXA may increase your risk of having a stroke or forming blood clots.**
- **Take PRADAXA exactly as prescribed by your doctor.**
- Take PRADAXA capsules twice a day (approximately every 12 hours).
- If you miss a dose of PRADAXA, take it as soon as you remember. If your next dose is less than 6 hours away, skip the missed dose. Do not take two doses of PRADAXA at the same time.
- Swallow PRADAXA capsules whole. Do not break, chew, or empty the pellets from the capsule.
- You can take PRADAXA with or without food.
- You should take PRADAXA with a full glass of water.

- Do not run out of PRADAXA. Refill your prescription before you run out. If you plan to have surgery, or a medical or a dental procedure, tell your doctor and dentist that you are taking PRADAXA. You may have to stop taking PRADAXA for a short time. See “What is the most important information I should know about PRADAXA?”.
- If you take too much PRADAXA, go to the nearest hospital emergency room or call your doctor.
- Call your doctor or healthcare provider right away if you fall or injure yourself, especially if you hit your head. Your doctor or healthcare provider may need to check you.
- PRADAXA comes in a bottle or in a blister package.
- Only open 1 bottle of PRADAXA at a time. Finish your opened bottle of PRADAXA before opening a new bottle.
- After opening a bottle of PRADAXA, use within 4 months. See “How should I store PRADAXA?”
- When it is time for you to take a dose of PRADAXA, only remove your prescribed dose of PRADAXA from your open bottle or blister package.
- Tightly close your bottle of PRADAXA right away after you take your dose.

What are the possible side effects of PRADAXA?

PRADAXA can cause serious side effects, including:

- See “What is the most important information I should know about PRADAXA?”
- Allergic Reactions. In some people, PRADAXA can cause symptoms of an allergic reaction, including hives, rash, and itching. Tell your doctor or get medical help right away if you get any of the following symptoms of a serious allergic reaction with PRADAXA:
 - chest pain or chest tightness
 - swelling of your face or tongue
 - trouble breathing or wheezing
 - feeling dizzy or faint

Common side effects of PRADAXA include:

- indigestion, upset stomach, or burning
- stomach pain

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of PRADAXA. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store PRADAXA?

- Store PRADAXA at room temperature between 59°F to 86°F (15°C to 30°C). After opening the bottle, use PRADAXA within 4 months. Safely throw away any unused PRADAXA after 4 months.
- **Keep PRADAXA in the original bottle or blister package to keep it dry (protect the capsules from moisture). Do not put PRADAXA in pill boxes or pill organizers.**
- **Tightly close your bottle of PRADAXA right away after you take your dose.**

Keep PRADAXA and all medicines out of the reach of children.

General information about PRADAXA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use PRADAXA for a condition for which it was not prescribed. Do not give your PRADAXA to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about PRADAXA. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about PRADAXA that is written for health professionals.

For more information, go to www.PRADAXA.com or call Boehringer Ingelheim Pharmaceuticals, Inc. at 1-800-542-6257 or (TTY) 1-800-459-9906, or scan here to go to www.PRADAXA.com.



What are the ingredients in PRADAXA?

Active ingredient: dabigatran etexilate mesylate

Inactive ingredients: acacia, dimethicone, hypromellose, hydroxypropyl cellulose, talc, and tartaric acid. The capsule shell is composed of carrageenan, FD&C Blue No. 2 (150 mg strength only), FD&C Yellow No. 6, hypromellose, potassium chloride, titanium dioxide, and black edible ink.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Distributed by:
Boehringer Ingelheim Pharmaceuticals, Inc.
Ridgefield, CT 06877 USA

Revised: January 2015

The brands listed above are trademarks of their respective owners and are not trademarks of Boehringer Ingelheim Pharmaceuticals, Inc. The owners of these brands are not affiliated with and do not endorse Boehringer Ingelheim Pharmaceuticals, Inc., or its products.

Copyright 2015 Boehringer Ingelheim Pharmaceuticals, Inc.
ALL RIGHTS RESERVED

75461-14
IT5060ACH192015

75457-14
IT5400Z

301841-09
IT5624N