



Read this important information before taking:



Pradaxa (dabigatran)

Take extra care! Pradaxa is a **high-alert medicine**.

This means that Pradaxa has been proven to be safe and effective, but serious harm, such as severe bleeding or a stroke, can occur if it is not taken exactly as directed.

When Your Doctor Prescribes Pradaxa (a blood thinner)



Tell

- ❑ 1 **Tell your doctor about all your diseases and conditions.** Pradaxa may not be right for you if you have any of the following: bleeding disorders, kidney or liver disease, stomach ulcers, problems with your heart valves, artificial heart valves, open wounds, if you are pregnant or plan to become pregnant, or if you tend to fall or are at risk for falls.
- ❑ 2 **Tell the doctor what else you take.** Certain medicines increase the risk of bleeding when taken with Pradaxa. Provide the doctor with a list of all the prescription, over-the-counter, and herbal medicines, vitamins, and other dietary supplements you take. While taking Pradaxa, tell your doctor if you start or stop any medicines or dietary supplements. Common over-the-counter and herbal medicines to avoid can be found on the other side of this page in the **Fast Facts** table. Also tell other doctors, dentists, and pharmacists that you are taking Pradaxa.
- ❑ 3 **Know why you take Pradaxa and how to take it.** Check that you understand how to take Pradaxa by telling the doctor why you are taking the medicine, what times of the day you will take it, what strength capsules you will take (75 mg, 110 mg, or 150 mg), and how many capsules you will take each time.



When Taking Pradaxa



- ❑ 4 **Take exactly as directed.** Take your Pradaxa at the same time or times each day and do not skip any doses. If you forget to take a dose, take it as soon as you remember if your next dose is more than 6 hours away. If your next dose is less than 6 hours away, skip the missed dose and take your next dose at the correct time. Do **NOT** take more than one dose at the same time to make up for a missed dose. Contact your doctor if you miss two or more doses.



- ❑ 5 **Swallow the capsules whole.** Do **NOT** break, open, crush, or chew the capsules. Taking Pradaxa without the capsule shell causes your body to absorb more of the medicine, which increases your risk of serious bleeding.



- ❑ 6 **Keep the medicine in its original package.** Pradaxa must be kept in the container it comes in from the pharmacy. Do not store the capsules in other containers, including daily or weekly pill holders. Only open one bottle at a time, and immediately close the bottle tightly after removing a capsule. Throw away any unused Pradaxa 4 months after opening the bottle.



- ❑ 7 **Do not stop the medicine.** Do not stop taking Pradaxa unless your doctor tells you to stop. Refill your prescription before you run out. Stopping the medicine may increase your risk of forming blood clots or having a stroke.



- ❑ 8 **Take precautions to prevent bleeding.** Avoid sharp objects, rough sports, and fall risks (climbing a ladder, for example) that can lead to bruising, cuts, or injuries. Use a soft toothbrush and electric razor, and blow your nose gently.

When You Should Call Your Doctor



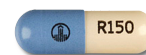
Call

- ❑ 9 **Call immediately** if you fall or injure yourself, especially if you hit your head, or if you experience any signs of bleeding, a blood clot, a stroke, or an allergic reaction, which are listed on the other side of this page. If you can't reach your doctor right away, seek immediate treatment in an emergency room.



- ❑ 10 **Call before** you have any dental work, surgery, a spinal or epidural injection, or any other type of medical procedure that may cause you to bleed. Your doctor may tell you to stop taking Pradaxa for a while. Ask your doctor to tell you when to start taking Pradaxa again after the procedure.

Pradaxa capsules come in three strengths (75 mg, 110 mg, and 150 mg). Each capsule is marked with a number that corresponds to the strength. Be sure the number on the capsule matches the strength you need for your prescribed dose.



75 mg

110 mg

150 mg

For more information to help keep you safe, visit: www.consumermedsafety.org.

Seek Medical Treatment **Immediately** if You Have Signs of **Bleeding, Blood Clot, Stroke, or Allergic Reaction**



Signs of **bleeding**

- Unusual pain, swelling, discomfort (may also be a sign of a clot)
- Unusual or easy bruising
- Pink, red, or brown urine
- Prolonged bleeding of gums or cuts
- Persistent, frequent nosebleeds
- Unusually heavy/long menstrual flow
- Coughing up blood clots
- Vomit that is bloody or looks like “coffee grounds”
- Severe dizziness, weakness, headache, fainting, unusual or persistent tiredness
- Bloody red or black tarry stools (poop)
- Joint pain



Signs of a **blood clot or stroke**

- **In the lung:** chest pain, fast heart rate, coughing, trouble breathing, fever
- **In the arm or leg:** sudden pain, swelling, redness, warmth, tenderness
- **In the brain (stroke):** headache; dizziness; seizure; vision changes; slurred speech or trouble speaking; weakness or tingling in the face, arm, or leg, especially on one side of body



Signs of an **allergic reaction**

- Skin rash or hives
- Itching
- Trouble breathing
- Wheezing
- Chest tightness
- Swollen face or tongue

Signs of a Stroke: Act **F.A.S.T.**



FACE
DROOPING



ARM
WEAKNESS



SPEECH
DIFFICULTY



TIME
TO CALL 911

Topics	Fast Facts
Generic name	■ dabigatran (pronounced da-BIG-a-tran)
Brand name	■ Pradaxa (no generic available)
Common uses	<ul style="list-style-type: none"> ■ Treat and prevent blood clots in the leg, arm, or lung ■ Reduce the risk of stroke and blood clots in patients with atrial fibrillation not caused by an abnormal heart valve ■ Prevent blood clots after hip replacement surgery (and sometimes after knee replacement surgery)
Usual dose	<ul style="list-style-type: none"> ■ Your dose will depend on why you take Pradaxa ■ Usual doses are 150 mg twice daily or 220 mg once daily ■ Your doctor may prescribe 75 mg twice daily if you have problems with kidney function
Special instructions	<ul style="list-style-type: none"> ■ Swallow the capsules whole; do NOT break, open, crush, or chew the capsules ■ Let your doctor know if you might have trouble paying for Pradaxa; your doctor may be able to help you get a discount or switch you to a less expensive medicine ■ Let your doctor know if you miss taking two or more doses of Pradaxa
Safety during pregnancy/ breastfeeding	<ul style="list-style-type: none"> ■ Speak with your healthcare provider if you are, or plan to become, pregnant or breastfeeding ■ It is not known if Pradaxa will harm an unborn baby or nursing baby ■ Bleeding in the mother may be a concern when the baby is born
Storage and disposal	<ul style="list-style-type: none"> ■ Store at room temperature in a dry place; do not store in a bathroom ■ Keep the capsules in the original container, lid tightly closed; do not put them in a pill holder ■ Once the container has been opened, throw away any unused Pradaxa after 4 months ■ Keep Pradaxa and all medicines out of the reach of children
Common side effects	■ If indigestion, heartburn, stomach pain, or acid reflux (sour stomach contents backing up into your throat) is a problem, contact your doctor
Side effects to report to your doctor immediately	<ul style="list-style-type: none"> ■ Signs of bleeding, blood clot, stroke, or allergic reaction (see top of page) ■ People 75 years and older have an increased risk of bleeding when taking Pradaxa
Over-the-counter medicines, herbals, or vitamins that should NOT be taken with Pradaxa UNLESS prescribed by your doctor	<ul style="list-style-type: none"> ■ Aspirin and aspirin-containing products ■ Nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen (Motrin, Advil) or naproxen (Aleve) ■ Herbals or vitamins with blood-thinning traits (e.g., ginger, garlic, ginkgo biloba, alfalfa, anise, bilberry, St. John's wort, feverfew, fish oil, vitamin E)
Prescription medicines that should NOT be taken with Pradaxa	<ul style="list-style-type: none"> ■ Tell your doctor and pharmacist about the medicines you take, since many medicines interact with Pradaxa ■ Especially tell your doctor if you take rifampin (Rifadin), dronedarone (Multaq), clopidogrel (Plavix), prasugrel (Effient), ticagrelor (Brilinta), ketoconazole tablets ■ Do not take other blood-thinning medicines, including apixaban (Eliquis), rivaroxaban (Xarelto), edoxaban (Savaysa), warfarin (Coumadin, Jantoven), enoxaparin (Lovenox), heparin
Special tests your doctor may prescribe	<ul style="list-style-type: none"> ■ Special tests are generally not needed to see if your blood-thinning level is in the right range ■ Your doctor should check your kidney function with a blood test before starting and while taking Pradaxa