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2. Pradaxa

Pradaxa ⊲

Generic name: dabigatran [da-BIG-a-tran]

Drug class: Thrombin inhibitors

Medically reviewed by Sophia Entringer, PharmD. Last updated on Feb 15, 2025.

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What is Pradaxa?

Pradaxa (dabigatran) belongs to a class of anticoagulant medications called direct thrombin inhibitors. Dabigatran works by preventing blood clots from forming in the body.

Pradaxa is used to treat blood clots deep in the body (deep vein thrombosis, DVT) and lungs (pulmonary embolism, PE) in adults who have received blood thinners by injection for 5 to 10 days.

Pradaxa is used to treat blood clots in children aged 3 months to less than 18 years of age who have been treated with an injectable blood thinner for at least 5 days.

Pradaxa is used in adults and children aged 3 months to less than 18 years of age to lower the risk of a blood clot coming back after receiving treatment for blood clots.

Pradaxa is also used after hip replacement surgery to prevent a blood clot deep in the body (deep vein thrombosis, DVT) or lungs (pulmonary embolism, PE).

Pradaxa is also used to lower the risk of stroke and blood clots in adults with atrial fibrillation (a heart rhythm disorder). This medicine is used when the atrial fibrillation is not caused by a heart valve problem.

Warnings

Pradaxa can cause you to bleed more easily. **Call your doctor at once if you have:** bleeding gums, nosebleeds, heavy menstrual periods or abnormal vaginal bleeding, blood in your urine, bloody or tarry stools, coughing up blood or vomit that looks like coffee grounds.

Many other drugs can increase your risk of bleeding when used with dabigatran. Tell your doctor about all medicines you have recently used.

Pradaxa can cause a very serious blood clot around your spinal cord if you undergo a spinal tap or receive spinal anesthesia (epidural), especially if you have a genetic spinal defect, if you have a spinal catheter in place, if you have a history of spinal surgery or repeated spinal taps, or if you are also using other drugs that can affect blood clotting. This type of blood clot can lead to long-term or permanent paralysis.

Get emergency medical help if you have **symptoms of a spinal cord blood clot** such as back pain, numbness or muscle weakness in your lower body, or loss of bladder or bowel control.

Do not stop taking Pradaxa without first talking to your doctor. Stopping suddenly can increase your risk of blood clot or stroke.

Before taking this medicine

You should not take Pradaxa if you are allergic to dabigatran, or if you have:

- · a mechanical prosthetic heart valve; or
- · active bleeding from a surgery, injury, or other cause.

Dabigatran can cause a serious blood clot if you undergo a procedure such as a spinal tap or receive spinal anesthesia (epidural). This type of blood clot could cause permanent or long-term paralysis.

Pradaxa can make it easier for you to bleed, even from a minor injury. Call your doctor if you have bleeding that will not stop.

To make sure Pradaxa is safe for you, tell your doctor if you have ever had:

- · a genetic spinal defect;
- a thin tube (catheter) placed in your back to give you certain medicine;
- a history of problems with your spine or a spinal surgery;
- a history of difficult or repeated spinal taps;
- bleeding problems;
- a stomach ulcer or bleeding in your stomach or intestines;
- take certain other medicines that can increase bleeding risk;
- antiphospholipid syndrome, an immune system disorder that increases the risk of blood clots;
- plan for surgery, or a medical or a dental procedure; or
- · kidney disease.

It is not known if dabigatran will harm an unborn baby. **Taking Pradaxa during pregnancy may cause bleeding in the mother or the unborn baby.** Tell your doctor if you are pregnant or plan to become pregnant.

You should not breastfeed while taking dabigatran.

1 Pradaxa pregnancy and breastfeeding warnings (more detail)

How should I take Pradaxa?

Take Pradaxa exactly as prescribed by your doctor. Follow all directions on your prescription label and read all medication guides or instruction sheets. Your doctor may occasionally change your dose.

Doses are based on weight in children and teenagers. Your child's dose may change if the child gains or loses weight.

Take Pradaxa capsule with a full glass of water. You may take this capsule with or without food.

Take with food if Pradaxa capsules upset your stomach.

Swallow the Pradaxa capsule whole and do not crush, chew, break, or open it.

Give Pradaxa oral pellets before a meal to make sure your child takes the full dose.

You may also mix the pellets with apple juice or soft food (apple sauce or apple juice, mashed carrots, or mashed bananas) at room temperature. Do not mix oral pellets with any other food, milk, milk products or any other liquid.

Mixed medicine should be used right away or within 30 minutes after mixing. Do not give this medicine using a syringe or through a feeding tube.

This medicine can also make it easier for you to bleed, even from a minor injury such as a fall or a bump on the head. Tell your doctor or seek emergency medical attention if you fall or hit your head, or have any bleeding that will not stop.

Your kidney function may need to be checked often.

Your doctor will determine how long you should take Pradaxa. **Do not change your dose or stop taking this** medication without your doctor's advice. Stopping suddenly can increase your risk of blood clots or stroke.

Tell any doctor who treats you that you are taking Pradaxa. If you need surgery or dental work, tell the surgeon or dentist ahead of time that you are taking this medication. If you need anesthesia for a medical procedure or surgery, you may need to stop taking Pradaxa for a short time.

If your child does not take all of the Pradaxa oral pellets, do not give another dose at that time and go back to the regular schedule.

Do not open more than one bottle of Pradaxa capsules at a time. Only open a new bottle after all the capsules in the previous bottle are gone.

Store Pradaxa capsules tightly closed at room temperature, away from moisture and heat. Keep the capsules in the original container or blister pack until you are ready to take the medicine. **Do not put Pradaxa capsules in a pill box or pill organizer.**

Throw away any unused Pradaxa capsules if it has been longer than 4 months since you first opened the bottle.

Store Pradaxa **oral pellets** at room temperature, away from moisture and heat. Keep the medicine in the original silver aluminum bag and do not open until you are ready to use the medicine. **Use the oral pellets within 6 months of opening the aluminum bag.**

Dosing information

Usual Adult Dose of Pradaxa for Deep Vein Thrombosis -- Prophylaxis:

Recommended doses: 150 mg orally twice a day.

Usual Adult Dose for Prevention of Thromboembolism in Atrial Fibrillation:

Recommended doses: 150 mg orally twice a day

Comments: Generally, the extent of anticoagulation does not need to be assessed with this drug; however, when necessary, use aPTT or ECT, and not INR to assess anticoagulant activity.

Uses: Reduction of risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation; treatment of deep venous thrombosis and pulmonary embolism in patients who have been treated with a parenteral anticoagulant for 5 to 10 days; reduction in the risk of recurrence of deep venous thrombosis and pulmonary embolism in patients who have been previously treated.

Usual Adult Dose of Pradaxa for Deep Vein Thrombosis/Pulmonary Embolism Prophylaxis Following Hip Replacement Surgery:

110 mg orally 1 to 4 hours after surgery and after hemostasis has been achieved, then 220 mg orally once a day for 28 to 35 days

Comments: If this drug is not started on the day of surgery, initiate treatment with 220 mg orally once a day after hemostasis has been achieved.

Use: For the prophylaxis of DVT and PE in adult patients who have undergone hip replacement surgery.

Usual Pediatric Dose of Pradaxa for Venous Thromboembolism:

Weigh-based dosage:

-11 kg to less than 16 kg: 75 mg twice daily
-16 kg to less than 26 kg: 110 mg twice daily
-26 kg to less than 41 kg: 150 mg twice daily
-41 kg to less than 61 kg: 185 mg twice daily

-61 kg to 81 kg: 220 mg twice daily -81 kg or greater: 260 mg twice daily

Comments:

- -This drug is to be used in children 8 years old or older that can swallow a capsule.
- -In treatment of VTE, treatment should be initiated following treatment with a parenteral anticoagulant for at least 5 days. For reduction of VTE recurrence, initiate treatment following previous treatment.
- -The concomitant treatment of this drug with P-gb inhibitors has not been studied in children and may increase the exposure to this drug.

Uses:

- -For the treatment of venous thromboembolic events (VTE) in pediatric patients 8 and older who have been treated with a parenteral anticoagulant for at least 5 days.
- -To reduce the risk of recurrence of VTE in pediatric patients 8 and older who have been previously treated.
- Detailed Pradaxa dosage information

What happens if I miss a dose?

Take the medicine as soon as you can, but skip the missed dose if your next dose is due in less than 6 hours. Do not use two doses at one time.

Get your prescription refilled before you run out of medicine completely.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

An overdose may cause excessive bleeding.

What should I avoid while taking Pradaxa?

Avoid activities that may increase your risk of bleeding or injury. Use extra care while shaving or brushing your teeth.

Pradaxa side effects

Get emergency medical help if you have **signs of an allergic reaction to Pradaxa**: hives; difficult breathing; swelling of your face, lips, tongue, or throat.

Also seek emergency medical attention if you have **symptoms of a spinal blood clot**: back pain, numbness, tingling, muscle weakness in your lower body, or loss of bladder or bowel control.

Pradaxa may cause serious side effects. Call your doctor at once if you have:

- bruising or bleeding that will not stop (nosebleeds, bleeding gums, heavy menstrual or vaginal bleeding);
- headache, weakness, dizziness, or feeling like you might pass out;
- bloody or tarry stools, coughing up blood or vomit that looks like coffee grounds;
- · urine that looks red, pink, or brown; or
- · unexpected pain, joint pain or swelling.

Common Pradaxa side effects include:

- · stomach pain or discomfort;
- upset stomach, burning;
- · bleeding;
- · heavy menstrual bleeding; or
- · nausea, vomiting, diarrhea.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Pradaxa side effects (more detail)

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What other drugs will affect Pradaxa?

Tell your doctor about all your current medicines. Many drugs can interact with dabigatran, especially:

- dronedarone;
- rifampin;
- ketoconazole;
- medicine used to prevent blood clots enoxaparin, warfarin, heparin, clopidogrel, dipyridamole, prasugrel, and others; or
- NSAIDs (nonsteroidal anti-inflammatory drugs) aspirin, ibuprofen (Advil, Motrin), naproxen (Aleve), celecoxib, diclofenac, indomethacin, meloxicam, and others.

This list is not complete and many other drugs may interact with dabigatran. This includes prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible drug interactions are listed here.

Pradaxa drug interactions (more detail)

Does Pradaxa interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

Pradaxa + Enter a drug name Add

Ingredients

Capsules

Active ingredient: dabigatran etexilate mesylate.

Inactive ingredients: acacia, dimethicone, hypromellose, hydroxypropyl cellulose, talc, and tartaric acid. The capsule shell is composed of carrageenan, hypromellose, potassium chloride, titanium dioxide, black edible ink, and FD& C Blue No. 2 (150 mg and 110 mg capsules only).

Oral Pellets

Active ingredient: dabigatran etexilate mesylate.

Inactive ingredients: acacia, dimethicone, hypromellose, hydroxypropyl cellulose, talc, and tartaric acid.

Manufacturer

Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877, USA.

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Professional resources

- Pradaxa prescribing information
- Pradaxa Oral Pellets (FDA)
- Dabigatran (AHFS Monograph)

Related treatment guides

- Prevention of Thromboembolism in Atrial Fibrillation
- Deep Vein Thrombosis, Prophylaxis
- Pulmonary Embolism
- Deep Vein Thrombosis
- Deep Vein Thrombosis/Pulmonary Embolism Prophylaxis Following Hip Replacement Surgery
- Venous Thromboembolism

Further information

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use Pradaxa only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

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DRUG STATUS

Availability

Rx Prescription only

Pregnancy & Lactation

& Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

10+ years FDA approved 2010

User Reviews & Ratings

Images

Pradaxa 150 mg (Logo R150)



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