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2. Dabigatran

# Dabigatran ⊲

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

Brand name: Pradaxa

Dosage forms: oral capsule (110 mg; 150 mg; 75 mg), oral granule (110 mg; 150 mg; 20 mg; 30 mg; 40 mg; 50 mg)

Drug class: Thrombin inhibitors



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## What is dabigatran?

Dabigatran 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.

Dabigatran 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.

Dabigatran 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.

Dabigatran 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).

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

Dabigatran may also be used for purposes not listed in this medication guide.

## Dabigatran side effects

Get emergency medical help if you have **signs of an allergic reaction**: 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.

#### Dabigatran 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 side effects of dabigatran may 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.

Dabigatran side effects (more detail)

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## Warnings

Do not stop taking dabigatran without your doctor's advice. Stopping it suddenly can increase your risk of blood clots or stroke.

Some drugs can increase your risk of bleeding when used with dabigatran. Tell your doctor about all other medicines you use.

Call your doctor at once if you have signs of bleeding such as: headaches, joint pain or swelling, feeling very weak or dizzy, bleeding gums, nosebleeds, heavy menstrual periods or abnormal vaginal bleeding, blood in your urine, bloody or tarry stools, coughing up blood, vomit that looks like coffee grounds or any bleeding that will not stop.

Dabigatran can cause a very serious blood clot around your spinal cord if you undergo a spinal tap or receive spinal anesthesia (epidural). Tell any doctor who treats you that you are taking dabigatran.

## Before taking this medicine

You should not take dabigatran if you are allergic to it, 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.

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

Tell your doctor if you have or 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 dabigatran 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.

## How should I take dabigatran?

Follow all directions on your prescription label and read all medication guides or instruction sheets. Your doctor may occasionally change your dose. Use the medicine exactly as directed.

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

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

Take with food if dabigatran capsules upset your stomach.

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

Give dabigatran 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 dabigatran 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 dabigatran. 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 dabigatran. 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 dabigatran for a short time.

If your child does not take all of the dabigatran **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 dabigatran **capsules** at a time. Only open a new bottle after all the capsules in the previous bottle are gone.

Store dabigatran **capsule** 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 dabigatran capsules in a pill box or pill organizer.** 

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

Store dabigatran **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.** 

1 Detailed Dabigatran 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 dabigatran?

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

## What other drugs will affect dabigatran?

Tell your doctor about all your current medicines. Many drugs can affect 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 affect dabigatran. This includes prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible drug interactions are listed here.

Dabigatran drug interactions (more detail)

## Does dabigatran interact with my other drugs?

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

dabigatran

Enter a drug name Add

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### **Patient resources**

- Dabigatran advanced reading
- Dabigatran Etexilate

### Other brands

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### **Professional resources**

- Dabigatran monograph
- Dabigatran Capsules (FDA)

### Other brands

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## Related treatment guides

- Prevention of Thromboembolism in Atrial Fibrillation
- Pulmonary Embolism
- Deep Vein Thrombosis
- Deep Vein Thrombosis, Prophylaxis

- 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 this medication 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**

প্ Risk data available

#### **CSA Schedule\***

N/A Not a controlled drug

### **Approval History**

Drug history at FDA

### **User Reviews & Ratings**

6.9 / 10

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### **Images**

Dabigatran Etexilate Mesylate 150 mg (H D11)



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