



A Patient's Guide to Taking Dabigatran Etexilate

Sarah A. Spinler, PharmD, BCPS (AQ Cardiology); Vincent J. Willey, PharmD



Dabigatran etexilate is a prescription medication used to slow and inhibit the formation of blood clots. Dabigatran is known by the trade name Pradaxa in the United States and all other countries in which it is marketed except Japan (Prazaxa) and Canada (Pradax). Although forming blood clots is a normal and important body function needed to stop bleeding, for some people the blood clot formation process can become harmful. For example, people with an irregular heart rhythm known as atrial fibrillation are at an increased risk of stroke because of the formation of harmful blood clots. Dabigatran is an anticoagulant type of medication. Anticoagulants prevent blood clots from forming. The medication warfarin (Coumadin) is another example of an anticoagulant. Anticoagulants are also commonly called blood thinners, although they work by preventing blood clot formation and not by making the blood thinner.

How Does Dabigatran Work?

The formation of blood clots in the body is a very complex process that requires multiple steps occurring in a particular order. Substances known as clotting factors are used and produced

in each step in the process. One of the final steps of clot formation involves a clotting factor known as thrombin. Dabigatran works in the blood by blocking the action of thrombin, which inhibits the clot-making process.

Tips on Taking Dabigatran

Dabigatran has been approved in the United States to reduce the risk of stroke and other harmful blood clots in people with nonvalvular atrial fibrillation. Dabigatran is available as a capsule in doses of 75 and 150 mg (Figure, A and B). The usual dose of dabigatran is a 150-mg capsule twice a day by mouth. For people with certain types of kidney problems, the dose may be decreased to 75 mg twice a day. The dabigatran capsule may be taken with or without food and must be swallowed whole. The capsule cannot be broken or chewed, and the pellets inside the capsule should not be sprinkled onto foods or into liquids.

Dabigatran should be taken as prescribed and should not be stopped without first talking to your doctor, because this may increase your risk of stroke. If you miss a dose, you should take that dose as soon as you remember. However, if you remember <6 hours from when you are scheduled to

take your next dose, you should skip the missed dose. You should not take 2 doses of dabigatran at the same time.

Your pharmacist will dispense dabigatran in the original bottle or in an individual unit dose blister package because the medication is sensitive to moisture (Figure, C and D). The medication must be stored in the original bottle with the lid tightly closed or in the original package at room temperature away from excessive moisture. The dabigatran capsules should not be placed or stored in another container, such as a pill box or pill organizer. Once the dabigatran bottle is opened, it must be used within 60 days or safely thrown away.

Differences Between Dabigatran and Warfarin

Although dabigatran and warfarin are both anticoagulants, there are significant differences between the medications. Whereas dabigatran is currently approved in the United States only for people with nonvalvular atrial fibrillation, warfarin has been approved for use in people not only with atrial fibrillation, but with other clotting diseases, such as blood clots in the leg veins or the lungs or after a heart attack.

From the Department of Pharmacy Practice and Pharmacy Administration, Philadelphia College of Pharmacy, University of the Sciences in Philadelphia, Philadelphia, PA.

Correspondence to Sarah A. Spinler, Philadelphia College of Pharmacy, University of the Sciences in Philadelphia, 600 S 43rd St, Philadelphia, PA 19104. E-mail s.spinle@usp.edu

(*Circulation*. 2011;124:e209-e211.)

© 2011 American Heart Association, Inc.

Circulation is available at <http://circ.ahajournals.org>

DOI: 10.1161/CIRCULATIONAHA.111.019786

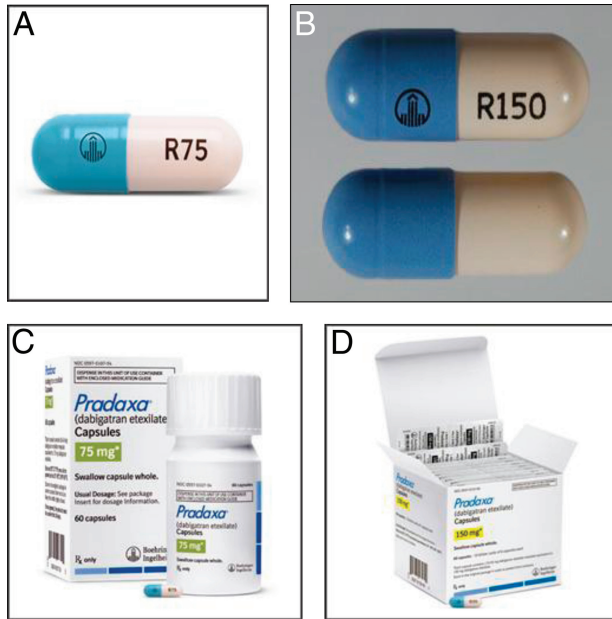


Figure. **A**, Dabigatran 75-mg capsule. **B**, Dabigatran 150-mg capsule. **C**, Dabigatran bottle. **D**, Dabigatran blister pack. The figure is reproduced with permission from Boehringer Ingelheim International GmbH. Further reproduction is prohibited without permission.

Warfarin needs to be monitored at least monthly with a blood test known as the prothrombin time test, most commonly reported as an international normalized ratio (INR). The prescriber adjusts the dose of warfarin according to the results of the INR. Dabigatran does not require INR testing because the same dose is used (adjusted for kidney function) with a consistent effect. Because the dose of dabigatran depends on a patient’s kidney function, some laboratory testing may be needed periodically.

Warfarin has more interactions with other medications that could increase or decrease its effectiveness. In addition, changes in diet, such as increased or decreased intake of certain foods containing vitamin K, may affect the ability of warfarin to prevent blood clots. Therefore, it is important that patients taking warfarin always let each of their healthcare providers know that they are taking the medication. Dabigatran appears not to be affected by most medications or food, but patients should still make sure to

alert all of their healthcare providers that they are taking the medication.

The inhibition of blood clots in people taking warfarin can be reversed by use of oral or intravenous vitamin K, which may be important to do if someone is at high risk for bleeding or is actively bleeding. At this time, there is no available medication to reverse the blood clot prevention effects of dabigatran. However, the effects of dabigatran on clotting wear off faster (in most people within 24 hours of stopping dabigatran) than the effects of warfarin, which takes days to wear off.

A research study comparing the efficacy and safety of dabigatran and warfarin in patients with nonvalvular atrial fibrillation found that patients taking dabigatran 150 mg twice daily had a 34% reduced risk of stroke compared with patients taking warfarin, with similar rates of major bleeding. Patients taking dabigatran 150 mg twice daily had more stomach upset and stopped taking their medication more often than patients taking warfarin.

Switching Between Dabigatran and Warfarin

If you and your healthcare provider determine that it would be in your best medical interest to switch from one oral anticoagulant medication to the other, it is important that you closely follow your healthcare provider’s instructions. When you switch from warfarin to dabigatran, your healthcare provider will instruct you to stop your warfarin, obtain INR levels, and start the dabigatran when the INR blood test reaches a certain level. When you switch from dabigatran to warfarin, your healthcare provider will have you start the warfarin up to 3 days before you stop the dabigatran.

Side Effects

The most important side effect associated with taking dabigatran is bleeding. You are at greater risk of bleeding if you have a history of bleeding, are older than 75 years of age, have kidney problems, have a stomach ulcer or

Table 1. Common Medications That Increase Risk of Bleeding

Medication	Trade Name	Prescription or Over the Counter
Aspirin	Multiple	OTC and prescription
Nonsteroidal antiinflammatory drugs	Multiple (Advil, Motrin, Aleve)	OTC and prescription
Warfarin	Coumadin, Jantoven	Prescription
Heparin	Not applicable	Prescription
Enoxaparin	Lovenox	Prescription
Dalteparin	Fragmin	Prescription
Clopidogrel	Plavix	Prescription
Prasugrel	Effient	Prescription
Aspirin plus dipyridamole	Aggrenox	Prescription

OTC indicates over-the-counter drugs.

Table 2. Common Do's and Don'ts of Dabigatran Therapy

What to Do	What Not to Do
<ul style="list-style-type: none"> Do watch for signs of bleeding. Do tell your prescriber if you injure yourself and experience bleeding. Do take dabigatran at the same time each day, about 12 hours apart. Do take a missed dose of dabigatran within 6 hours or else skip the dose and take the next one when scheduled. Do tell all of your healthcare providers and dentist that you are taking the blood thinner dabigatran. Do contact your pharmacy for refills before you run out. If in a bottle, store dabigatran in the original bottle with the lid tightly closed. Wear a medical identification bracelet or carry a medical identification card that indicates that you take an anticoagulant or blood thinner. 	<ul style="list-style-type: none"> Never double a dose if you miss a dose. Don't take dabigatran stored in bottles if it has been longer than 60 days since the bottle has been opened.

other problems with stomach or intestinal bleeding, or are taking other medications that also increase your risk of bleeding (Table 1). Check with your doctor before discontinuing any prescribed medications. Any unusual bleeding (including bleeding from the gums or nose, excessive menstrual bleeding, pink or brown urine, red or black stools, bruising, coughing or vomiting blood); severe, persistent headache; or dizziness should be reported to your healthcare provider immediately. The most common side effects from dabigatran are those associated with the stomach, such as indigestion, upset stomach, and stomach pain.

When to Call Your Healthcare Provider

You should call your healthcare provider or get immediate medical help if

you have any of these signs or symptoms of bleeding:

- Unexpected or uncontrollable bleeding
- Coughing or vomiting blood
- Red or black stools
- Severe, persistent headache, dizziness, or weakness
- Fall or injury to the head

Dabigatran and Lifestyle

Because dabigatran is an anticoagulant, care must be taken when you undertake activities that increase your risk of serious injury. Stopping dabigatran abruptly or missing doses increases your risk of stroke. It is important to know the common do's and don'ts of dabigatran therapy (Table 2).

Pregnancy

Dabigatran has not been shown to damage the fetus in animal reproduc-

tion studies but has not been studied in pregnant women. Potential benefits of taking dabigatran while pregnant may outweigh the risks. A woman who becomes pregnant or plans to become pregnant while taking dabigatran should notify her prescriber or doctor immediately to discuss potential risks versus benefits of continuing dabigatran.

Surgery and Dental and Other Medical Procedures

It is important to tell your healthcare providers that you are taking dabigatran if you need to have any surgery, dental work, or other medical procedures that increase your risk for bleeding. Dabigatran may need to be stopped temporarily.

Where to Get More Information

Your pharmacist will give you a dabigatran medication guide with each prescription. You should read the medication guide with each refill, because there may be new information. Ask your pharmacist or prescriber any questions you have. Keep a journal with your questions to ask them at your next visit. Reliable information about dabigatran and atrial fibrillation may also be found on the Internet at North American Thrombosis Forum (<http://www.natfonline.org>) Resources for Patients and Caregivers, as well as ClotCare Online Resource (<http://www.ClotCare.org>) and the Heart Rhythm Society (<http://www.hrsonline.org>) Patient Information.

Disclosures

Dr Spinler consults for Daiichi Sankyo. Dr Willey reports no conflicts.

KEY WORDS: anticoagulants ■ atrial fibrillation ■ stroke prevention