PATIENT & CAREGIVER EDUCATION

Dabigatran Etexilate

This information from UpToDate® Lexidrug™ explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Pradaxa

Brand Names: Canada

APO-Dabigatran; Pradaxa

Warning

- Do not stop taking this drug without talking to the doctor who ordered it for you. Stopping this drug when you are not supposed to may raise the chance of blood clots. This includes stroke in certain people. You may need to stop this drug before certain types of dental or health care. Your doctor will tell you when to start taking it again. Follow what your doctor tells you closely.
- People who have any type of spinal or epidural procedure are more likely to have bleeding problems around the spine when already on this drug. This bleeding rarely happens, but can lead to not being able to move body (paralysis) long-term or paralysis that will not go away. The risk is raised in people who have problems with their spine, a certain type of epidural catheter, or have had spinal surgery. The risk is also raised in people who take any other drugs that may affect blood clotting, like blood-thinner drugs (like warfarin), aspirin, or nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen or naproxen.
- Tell your doctor you use this drug before you have a spinal or epidural procedure. Call your doctor right away if you have any signs of nerve problems like back pain, numbness or tingling, muscle weakness, paralysis, or loss of bladder or bowel control.
- Talk with your doctor if you have recently had or will be having a spinal or epidural procedure. Some time may need to pass between the use of this drug and your procedure. Talk with your doctor.

What is this drug used for?

- It is used to treat or prevent blood clots.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have bleeding problems.
- If you have had or plan to have a heart valve replaced.
- If you have kidney problems.
- If you have antiphospholipid syndrome (APS).
- If you are taking any of these drugs: Dronedarone or ketoconazole.
- If you are taking rifampin.
- If you are using another drug like this one. If you are not sure, ask your doctor or pharmacist.
- If you are breast-feeding. Do not breast-feed while you take this drug.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

For all patients taking this drug:

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists. This drug may need to be stopped before certain types of surgery as your doctor has told you. If this drug is stopped, your doctor will tell you when to start taking this drug again after your surgery or procedure.
- Have your blood work and other lab tests checked as you have been told by

your doctor.

- You may bleed more easily. Be careful and avoid injury. Use a soft toothbrush and an electric razor. Rarely, some bleeding problems have been deadly.
- If you fall or hurt yourself, or if you hit your head, call your doctor right away. Talk with your doctor even if you feel fine.
- If you are 65 or older, use this drug with care. You could have more side effects.
- If you are pregnant or you get pregnant while taking this drug, call your doctor right away.

Children:

- If giving this drug to your child and your child's weight changes, talk with the doctor. The dose of this drug may need to be changed.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of bleeding like throwing up or coughing up blood; vomit that looks like coffee grounds; blood in the urine; black, red, or tarry stools; bleeding from the gums; abnormal vaginal bleeding; bruises without a cause or that get bigger; or bleeding you cannot stop.
- Chest pain.
- Dizziness or passing out.

- Weakness on 1 side of the body, trouble speaking or thinking, change in balance, drooping on one side of the face, or blurred eyesight.
- Feeling confused.
- Feeling very tired or weak.
- Severe headache or throwing up.
- Very bad swelling.
- Joint pain or swelling.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

For all patients taking this drug:

- Upset stomach.
- Stomach pain or heartburn.

Children:

- Diarrhea.
- Throwing up.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1-800-332-1088. You may also report side effects at https://www.fda.gov/medwatch.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

Capsules:

- Take with or without food. Take with food if it causes an upset stomach.
- Swallow whole. Do not chew, open, or crush.
- Take with a full glass of water.
- If you are taking 2 doses in a day, take doses about 12 hours apart.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.
- If you have trouble swallowing, talk with your doctor.

Oral pellets:

- Do not open until you are ready to use.
- Take this drug before meals.
- Sprinkle the pellets on a small amount of mashed carrots, apple sauce, or mashed banana. The soft food needs to be at room temperature. Mix well and swallow. Do not mix with milk or soft foods that have milk products. Do not use a syringe to take this drug.
- Take your dose within 30 minutes after mixing. Throw away any part not used within 30 minutes of mixing.
- This drug may also be taken with apple juice. If using apple juice, follow how to use as you have been told or read the package insert.
- Do not put this drug down a feeding tube.
- If you are taking 2 doses in a day, take doses about 12 hours apart.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it is less than 6 hours until the next dose, skip the missed dose and go back to the normal time.
- Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

All products:

- Store at room temperature in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

Capsules:

- Keep capsules in the bottle they come in and do not move to a pill holder.
- Keep lid tightly closed.
- Throw away any unused capsules left in bottle after 4 months.

Oral pellets:

- Keep the unused packets in the aluminum bag. Use the packets within 6 months after opening the aluminum bag.
- Each aluminum bag has a desiccant (protects the drug from moisture) in it. After opening the aluminum bag, throw away the desiccant.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- This drug comes with an extra patient fact sheet called a Medication Guide. Read it with care. Read it again each time this drug is refilled. If you have any questions about this drug, please talk with the doctor, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient. UpToDate, Inc. and its affiliates disclaim any warranty or liability relating to this information or the use thereof. The use of this information is governed by the Terms of Use, available at https://www.wolterskluwer.com/en/know/clinical-effectiveness-terms.

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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