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 giving this drug without talking to the doctor who ordered it for your child. Stopping this drug when your child is not supposed to may raise the chance of blood clots. This includes stroke in certain people. Your child may need to stop this drug before certain types of dental or health care. The doctor will tell you when to start giving it again. Follow what the 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 the doctor your child uses this drug before your child has a spinal or epidural procedure. Call the doctor right away if your child has any signs of nerve problems like back pain, numbness or tingling, muscle weakness, paralysis, or loss of bladder or bowel control.
- Talk with the doctor if your child has 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 child's procedure. Talk with your child's doctor.

What is this drug used for?

- It is used to treat or prevent blood clots.

What do I need to tell the doctor BEFORE my child takes this drug?

- If your child is allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell the doctor about the allergy and what signs your child had.
- If your child has bleeding problems.
- If your child has had or will be having a heart valve replaced.
- If your child has kidney problems.
- If your child has antiphospholipid syndrome (APS).
- If your child is taking any of these drugs: Dronedarone, ketoconazole, or rifampin.
- If your child is using another drug like this one. If you are not sure, ask your child's doctor or pharmacist.

If your child is breast-feeding a baby:

- Be sure your child does not breast-feed a baby while taking this drug.

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

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

What are some things I need to know or do while my child takes this drug?

- Tell all of your child's health care providers that your child is taking this drug. This includes your child's doctors, nurses, pharmacists, and dentists. This drug may need to be stopped before certain types of surgery as the doctor has told you. If this drug is stopped, the doctor will tell you when to start

giving this drug again after your child's surgery or procedure.

- Have your child's blood work and other lab tests checked as you have been told by the doctor.
- Your child may bleed more easily. Make sure your child is careful and avoids injury. Be sure your child has a soft toothbrush. Rarely, some bleeding problems have been deadly.
- If your child falls, gets hurt, or hits their head, call the doctor right away. Talk with the doctor even if your child feels fine.
- 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.

If your child is pregnant:

- If your child is pregnant or gets pregnant while taking this drug, call the doctor right away.

What are some side effects that I need to call my child's 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 child's doctor or get medical help right away if your child has 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 child's doctor or get medical help if any of these side effects or any other side effects bother your child or do not go away:

- Diarrhea, upset stomach, or throwing up.
- Stomach pain or heartburn.

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

You may report side effects to your national health agency.

How is this drug best given?

Give this drug as ordered by your child's doctor. Read all information given to you. Follow all instructions closely.

Capsules:

- Give with or without food. Give with food if it causes your child to have an upset stomach.
- Have your child swallow whole. Do not let your child chew, open, or crush.
- Give this drug with a full glass of water.

- Give doses about 12 hours apart.
- Keep giving this drug to your child as you have been told by your child's doctor or other health care provider, even if your child feels well.
- If your child has trouble swallowing, talk with the doctor.

Oral pellets:

- Do not open until you are ready to use.
- Give 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 have your child swallow. Do not mix with milk or soft foods that have milk products. Do not use a syringe to give this drug.
- Give your child the 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.
- Give doses about 12 hours apart.
- Keep giving this drug to your child as you have been told by your child's doctor or other health care provider, even if your child feels well.

What do I do if my child misses a dose?

- Give 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 give 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 child's symptoms or health problems do not get better or if they become worse, call your child's doctor.
- Do not share your child's drug with others and do not give anyone else's drug to your child.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your child's doctor, nurse, 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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