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Dabigatran

pronounced as (da" bi gat' ran)

IMPORTANT WARNING:

If you have atrial fibrillation (a condition in which the heart beats irregularly, increasing the chance of clots forming in the body, and possibly causing strokes) and are taking dabigatran to help prevent strokes or serious blood clots, you are at a higher risk of having a stroke after you stop taking this medication. Do not stop taking dabigatran without talking to your doctor. Continue to take dabigatran even if you feel well. Be sure to refill your prescription before you run out of medication so that you will not miss any doses of dabigatran. If you need to stop taking dabigatran, your doctor may prescribe another anticoagulant ('blood thinner') to help prevent a blood clot from forming and causing you to have a stroke.

If you have epidural or spinal anesthesia or a spinal puncture while taking a 'blood thinner' such as dabigatran, you are at risk of having a blood clot form in or around your spine that could cause you to become paralyzed. Tell your doctor if you have an epidural catheter that is left in your body or have or have ever had repeated epidural or spinal punctures, spinal deformity, or spinal surgery. Tell your doctor and pharmacist if you are taking any of the following: anagrelide (Agrylin), aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen (Advil, Motrin), indomethacin (Indocin, Tivorbex), ketoprofen, and naproxen (Aleve, Anaprox, others), cilostazol (Pletal), clopidogrel (Plavix), dipyridamole (Persantine), eptifibatide (Integrilin), heparin, prasugrel (Effient), ticagrelor (Brilinta), ticlopidine, tirofiban (Aggrastat), and warfarin (Coumadin, Jantoven). If you experience any of the following symptoms, call your doctor immediately: back pain, muscle weakness (especially in your legs and feet), numbness or tingling (especially in your legs), or loss of control of your bowels or bladder.

Keep all appointments with your doctor and the laboratory. Your doctor may order certain lab tests to check your body's response to dabigatran.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with dabigatran and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>)

[<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>]) or the manufacturer's website to obtain the Medication Guide.

Why is this medication prescribed?

Dabigatran is used to treat deep vein thrombosis (DVT; a blood clot, usually in the leg) and pulmonary embolism (PE; a blood clot in the lung) in adults and children 3 months of age and older who have been treated with an injectable anticoagulant ('blood thinner'). It is also used to reduce the risk of a DVT and PE from happening again after initial treatment is completed in adults and children 3 months of age and older. Dabigatran is used to help prevent DVT and PE in adults who have had hip replacement surgery. Dabigatran is also used to help prevent strokes or serious blood clots in adults who have atrial fibrillation (a condition in which the heart beats irregularly, increasing the chance of clots forming in the body, and possibly causing strokes) without heart valve disease. Dabigatran is in a class of anticoagulant medications called direct thrombin inhibitors. It works by preventing blood clots from forming in the body.

How should this medicine be used?

Dabigatran comes as a capsule and pellets to take by mouth. When dabigatran is used to treat or prevent a DVT or PE or to prevent strokes or serious blood clots in people who have atrial fibrillation, it is usually taken twice a day. When dabigatran is used to prevent a DVT or PE after hip replacement surgery, it is usually taken 1 to 4 hours after surgery, and then once a day for another 28 to 35 days. Dabigatran capsules may be taken with or without food. Take dabigatran capsules with food if the medication upsets your stomach. Give dabigatran pellets before meals to make sure your child receives the full dose. Take dabigatran at around the same times every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take dabigatran exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the capsules whole with a whole glass of water; do not split, chew, or crush them. Do not open the capsules and sprinkle the contents on food or into drinks.

Dabigatran pellets should be taken with soft foods or apple juice. Do not mix the pellets with milk or foods that contain milk products. To prepare a dose of dabigatran pellets with soft food, sprinkle the entire packet of pellets on soft food such as baby rice cereal (prepared with water), mashed carrots, mashed banana, or applesauce. Give the entire mixture within 30 minutes of sprinkling the pellets on the soft food. Alternatively you can give dabigatran pellets to your child along with apple juice. Spoon the pellets into your child's mouth and offer them as much apple juice as necessary to swallow the pellets. Or you can mix the pellets in small amount of apple juice and have your child drink the entire mixture. If pellets stick to the cup, add a small amount of apple juice and give it to your child. Repeat as necessary until all of the pellets are gone. Do not store the mixture of dabigatran pellets and soft food or apple juice; use within 30 minutes after mixing.

If your child does not take the entire dose of dabigatran pellets, do not give another dose at this time. Continue with the next dose at the scheduled time.

Dabigatran will help prevent strokes and blood clots only as long as you continue to take it. Continue to take dabigatran even if you feel well. Make sure to refill your prescription before you run out of medication so that you will not miss doses of dabigatran. Do not stop taking dabigatran without talking to your doctor. If you suddenly stop taking dabigatran, the risk that you will have clot or a stroke may increase.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking dabigatran,

- tell your doctor and pharmacist if you are allergic to dabigatran, any other medications, or any of the ingredients in dabigatran capsules or pellets. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: dronedarone (Multaq), ketoconazole (Nizoral), and rifampin (Rifadin, Rimactane, in Rifamate, in Rifater). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have had a valve in your heart replaced or if you have recently noticed any unusual bruising or bleeding. Your doctor probably will tell you not to take dabigatran.
- tell your doctor if you have or have ever had a bleeding problem, bleeding or an ulcer in your stomach or intestine; or kidney disease.
- tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. If you become pregnant while taking dabigatran, call your doctor. Taking dabigatran may increase the risk that you will experience severe bleeding during labor and delivery.
- talk to your doctor about the risks and benefits of taking dabigatran if you are 75 years of age or older.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking dabigatran.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if you remember the missed dose less than 6 hours before your next scheduled dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Dabigatran may cause side effects. Tell your doctor if any of these symptoms occur:

- stomach pain

- upset stomach
- heartburn
- nausea

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately or get emergency medical treatment:

- unusual bruising or bleeding
- pink or brown urine
- red or black, tarry stools
- coughing up blood
- vomiting material that is bloody or looks like coffee grounds
- bleeding from the gums
- frequent nosebleeds
- heavy menstrual bleeding
- bleeding from a cut that lasts longer than normal
- joint pain or swelling
- headache
- dizziness or feeling faint
- weakness
- hives
- rash
- itching
- difficulty breathing or swallowing
- chest pain or tightness
- swelling of the face, throat, tongue, lips, eyes, arms, hands, feet, ankles, or lower legs

Dabigatran may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Do not store dabigatran capsules in a pillbox or pill organizer. Store it at room temperature and away from excess heat and moisture. Open only one bottle of dabigatran capsules at a time. Finish your opened bottle of dabigatran capsules before opening a new bottle. Dispose of any capsules that are left in the container 4 months after you opened it. Keep the individual dabigatran pellet packets sealed in the aluminum bag until you are ready to use them. Dispose of any unused pellet packets 6 months after opening the aluminum bag.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include the following:

- unusual bruising or bleeding
- pink or brown urine
- red or black, tarry stools
- vomiting material that is bloody or looks like coffee grounds
- coughing up blood

What other information should I know?

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Pradaxa[®]

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