

MEDICATION GUIDE

Dabigatran Etexilate (DA-bi-GAT-ran E-tex-i-late) Capsules

This Medication Guide is for dabigatran etexilate capsules.

Read this Medication Guide before you start taking dabigatran etexilate capsules and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about dabigatran etexilate capsules?

- People with atrial fibrillation (a type of irregular heartbeat) are at an increased risk of forming a blood clot in the heart, which can travel to the brain, causing a stroke, or to other parts of the body. Dabigatran etexilate capsule lowers your chance of having a stroke by helping to prevent clots from forming. If you stop taking dabigatran etexilate capsules, you may have increased risk of forming a clot in your blood.

Do not stop taking dabigatran etexilate capsules without talking to the healthcare provider who prescribes it for you. Stopping dabigatran etexilate capsules increases your risk of having a stroke.

Dabigatran etexilate capsules may need to be stopped, if possible, before surgery or a medical or dental procedure. Ask the healthcare provider who prescribed dabigatran etexilate capsules for you when you should stop taking it. Your healthcare provider will tell you when you may start taking dabigatran etexilate capsules again after your surgery or procedure. If you have to stop taking dabigatran etexilate capsules, your healthcare provider may prescribe another medicine to help prevent a blood clot from forming.

- Dabigatran etexilate capsules can cause bleeding which can be serious, and sometimes lead to death. This is because dabigatran etexilate capsule is a blood thinner medicine that lowers the chance of blood clots forming in your body.

• You may have a higher risk of bleeding if you take dabigatran etexilate capsules and:

- o are over 75 years old
- o have kidney problems
- o have stomach or intestine bleeding that is recent or keeps coming back, or you have a stomach ulcer
- o take other medicines that increase your risk of bleeding, including:
 - aspirin or aspirin-containing products
 - long-term (chronic) use of non-steroidal anti-inflammatory drugs (NSAIDs)
 - a medicine that contains warfarin sodium
 - a medicine that contains heparin
 - a medicine that contains clopidogrel bisulfate
 - a medicine that contains prasugrel
- o have certain kidney problems and also take a medicine that contains dronedarone or ketoconazole tablets.

Tell your healthcare provider if you take any of these medicines. Ask your healthcare provider or pharmacist if you are not sure if your medicine is one listed above.

- Dabigatran etexilate capsules can increase your risk of bleeding because it lessens the ability of your blood to clot. During treatment with dabigatran etexilate capsules:

- o you may bruise more easily
- o it may take longer for any bleeding to stop

Call your healthcare provider or get medical help right away if you have any of these signs or symptoms of bleeding:

- o unexpected bleeding or bleeding that lasts a long time, such as:
 - unusual bleeding from the gums
 - nose bleeds that happen often
 - menstrual bleeding or vaginal bleeding that is heavier than normal
- o bleeding that is severe or you cannot control
- o pink or brown urine
- o red or black stools (looks like tar)
- o bruises that happen without a known cause or get larger
- o cough up blood or blood clots
- o vomit blood or your vomit looks like "coffee grounds"
- o unexpected pain, swelling, or joint pain
- o headaches, feeling dizzy or weak

Take dabigatran etexilate capsules exactly as prescribed. Do not stop taking dabigatran etexilate capsules without first talking to the healthcare provider who prescribes it for you. Stopping dabigatran etexilate capsules may increase your risk of a stroke.

- **Spinal or epidural blood clots (hematoma).** People who take a blood thinner medicine (anticoagulant) like dabigatran etexilate capsules, and have medicine injected into their spinal and epidural area, or have a spinal puncture have a risk of forming a blood clot that can cause long-term or permanent loss of the ability to move (paralysis). Your risk of developing a spinal or epidural blood clot is higher if:

- o a thin tube called an epidural catheter is placed in your back to give you certain medicine
- o you take NSAIDs or a medicine to prevent blood from clotting
- o you have a history of difficult or repeated epidural or spinal punctures
- o you have a history of problems with your spine or have had surgery on your spine

If you take dabigatran etexilate capsules and receive spinal anesthesia or have a spinal puncture, your healthcare provider should watch you closely for symptoms of spinal or epidural blood clots. Tell your healthcare provider right away if you have back pain, tingling, numbness, muscle weakness (especially in your legs and feet), loss of control of the bowels or bladder (incontinence).

See “What are the possible side effects of dabigatran etexilate capsules?” for more information about side effects.

What are dabigatran etexilate capsules?

Dabigatran etexilate capsules are a prescription medicine that is used to:

- **in adults:**

- o reduce the risk of stroke and blood clots in adults who have a medical condition called atrial fibrillation that is not caused by a heart valve problem. With atrial fibrillation, part of the heart does not beat the way it should. This can lead to blood clots forming and increase your risk of a stroke.
- o treat blood clots in the veins of your legs (deep vein thrombosis) and lungs (pulmonary embolism) after you have been treated with an injectable medicine to treat your blood clots for 5 to 10 days.
- o reduce your risk of blood clots from happening again in the veins of your legs (deep vein thrombosis) and lungs (pulmonary embolism) after you have received treatment for blood clots.
- o help prevent blood clots in your legs (venous thrombosis) and lungs (pulmonary embolism) after you have just had hip replacement surgery.

- **in children:**

- o treat blood clots in children 8 years to less than 18 years of age who have received an injectable medicine to treat their blood clots for at least 5 days.
- o reduce the risk of blood clots from happening again in children 8 years to less than 18 years of age who have received treatment for blood clots.

It is not known if dabigatran etexilate capsules are safe and effective in children with atrial fibrillation not caused by a heart valve problem, or in children who have undergone hip replacement surgery.

Do not take dabigatran etexilate capsules if you:

- currently have certain types of abnormal bleeding. Talk to your healthcare provider before taking dabigatran etexilate capsules if you currently have unusual bleeding.
- have had a serious allergic reaction to any of the ingredients in dabigatran etexilate capsules. See the end of this Medication Guide for a complete list of ingredients in dabigatran etexilate capsules. Ask your healthcare provider if you are not sure.
- have ever had or plan to have a valve in your heart replaced with a mechanical (artificial) prosthetic heart valve

Before taking dabigatran etexilate capsules, tell your healthcare provider about all of your medical conditions, including if you:

- have kidney problems
- have ever had bleeding problems
- have ever had stomach ulcers
- have antiphospholipid syndrome (APS)
- are pregnant or plan to become pregnant. It is not known if dabigatran etexilate capsules will harm your unborn baby. Tell your healthcare provider right away if you become pregnant during treatment with dabigatran etexilate capsules.
Females who are able to become pregnant: Talk with your healthcare provider about pregnancy planning during treatment with dabigatran etexilate capsules. Talk with your healthcare provider about your risk for severe uterine bleeding if you are treated with blood thinner medicines, including dabigatran etexilate capsules.
- are breastfeeding or plan to breastfeed. It is not known if dabigatran passes into your breast milk. You should not breastfeed during treatment with dabigatran etexilate capsules. Talk to your healthcare provider about the best way to feed your baby during treatment with dabigatran etexilate capsules.

Tell all of your healthcare providers and dentists that you are taking dabigatran etexilate capsules. They should talk to the healthcare provider who prescribed dabigatran etexilate capsules for you before you have **any** surgery or a medical or dental procedure.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some of your other medicines may affect the way dabigatran etexilate capsules works. Certain medicines may increase your risk of bleeding. See **“What is the most important information I should know about dabigatran etexilate capsules?”**

Especially tell your healthcare provider if you take a medicine that contains rifampin.

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take dabigatran etexilate capsules?

- Dabigatran etexilate comes as capsules and oral pellets. If you have a child who is older than 8 years of age and who is prescribed dabigatran etexilate, your healthcare provider will prescribe the type of dabigatran etexilate that is right for your child.
- Your healthcare provider will decide how long you should take dabigatran etexilate capsules. **Do not stop taking dabigatran etexilate capsules without first talking with your healthcare provider. Stopping dabigatran etexilate capsules may increase your risk of having a stroke or forming blood clots.**
- **Take dabigatran etexilate capsules exactly as prescribed by your healthcare provider.**
- If dabigatran etexilate capsule is prescribed for your child, your healthcare provider will determine the correct dose of dabigatran etexilate capsules for your child based on their weight. Your healthcare provider may increase or decrease your child's dose as they grow during treatment and as needed.
- **In adults:** Take dabigatran etexilate capsules 2 times a day. If you are taking dabigatran etexilate capsules after hip replacement surgery, take dabigatran etexilate capsules 1 time a day.

- **In children:** Take dabigatran etexilate capsules 2 times a day. Take 1 dose in the morning and 1 dose in the evening about every 12 hours, at about the same time each day.
- You can take dabigatran etexilate capsules with or without food. Taking dabigatran etexilate capsules with food may help if you have an upset stomach.
- Swallow dabigatran etexilate capsules whole with a full glass of water. Tell your healthcare provider if you or your child are not able to swallow the capsules whole. Do not break, chew, or empty the pellets from the capsule.
- **Do not** run out of dabigatran etexilate capsules. Refill your prescription before you run out. If you plan to have surgery, or a medical or a dental procedure, tell your healthcare provider and dentist that you are taking dabigatran etexilate capsules. You may have to stop taking dabigatran etexilate capsules for a short time. See **“What is the most important information I should know about dabigatran etexilate capsules?”**
- If you miss a dose of dabigatran etexilate capsules, take it as soon as you remember. If your next dose is less than 6 hours away, skip the missed dose. Do not take two doses of dabigatran etexilate capsules at the same time.
- If you take too much dabigatran etexilate capsules, go to the nearest hospital emergency room or call your healthcare provider.
- Call your healthcare provider right away if you fall or injure yourself, especially if you hit your head. Your healthcare provider may need to check you.
- Dabigatran etexilate capsules come in a bottle or in a blister package.
- Only open 1 bottle of dabigatran etexilate capsules at a time. Finish your opened bottle of dabigatran etexilate capsules before opening a new bottle.
- After opening a bottle of dabigatran etexilate capsules, use within 4 months. See **“How should I store dabigatran etexilate capsules?”**
- When it is time for you to take a dose of dabigatran etexilate capsules, only remove your prescribed dose of dabigatran etexilate capsules from your open bottle or blister package.
- Tightly close your bottle of dabigatran etexilate capsules right away after you take your dose.

What are the possible side effects of dabigatran etexilate capsules?

Dabigatran etexilate capsules can cause serious side effects. See **“What is the most important information I should know about dabigatran etexilate capsules?”**

- **Allergic Reactions.** Some adults taking dabigatran etexilate capsules have developed symptoms of an allergic reaction.
 - o Call your healthcare provider if you or your child gets symptoms of an allergic reaction, such as:
 - hives
 - rash
 - itching
 - o **Get medical help right away if you or your child gets any of the following symptoms of a serious allergic reaction with dabigatran etexilate capsules:**
 - chest pain or chest tightness
 - trouble breathing or wheezing
 - swelling of your face or tongue
 - feeling dizzy or faint

Common side effects of dabigatran etexilate capsules in adults and children include:

- indigestion, upset stomach, or burning
- stomach-area (abdominal) pain or discomfort

In children, common side effects also include:

- nausea, vomiting, or diarrhea

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of dabigatran etexilate capsules. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store dabigatran etexilate capsules?

- Store dabigatran etexilate capsules at room temperature 68°F to 77°F (20°C to 25°C).
- After opening the bottle, use dabigatran etexilate capsules within 4 months. Safely throw away any unused dabigatran etexilate capsules after 4 months.
- **Keep dabigatran etexilate capsules in the original bottle or blister package to keep them dry (protect the capsules from moisture). Do not put dabigatran etexilate capsules in pill boxes or pill organizers.**
- **Tightly close your bottle of dabigatran etexilate capsules right away after you take your dose.**
- Bottle of dabigatran etexilate capsules come in a child-resistant package.

Keep dabigatran etexilate capsules and all medicines out of the reach of children.

General information about the safe and effective use of dabigatran etexilate capsules

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use dabigatran etexilate capsules for a condition for which it was not prescribed. Do not give dabigatran etexilate capsules to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about dabigatran etexilate capsules. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about dabigatran etexilate capsules that is written for health professionals.

What are the ingredients in dabigatran etexilate capsules?

Active ingredient: dabigatran etexilate mesylate

Inactive ingredients: hydroxypropyl cellulose, hypromellose phthalate, pelletized tartaric acid, talc. The capsule shell is composed of carrageenan, hypromellose, potassium chloride and titanium dioxide. Additionally, 110 mg and 150 mg capsule shell also contains FD&C Blue No. 2.

The empty hard hypromellose capsule shells are printed with edible black ink containing iron oxide black, potassium hydroxide and shellac.
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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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