

MEDICATION GUIDE
BEVYXXA® (BEV vix a)
capsules

What is the most important information I should know about BEVYXXA?

BEVYXXA can cause serious side effects, including:

- **Bleeding problems.** BEVYXXA can increase the risk of bleeding, which can be serious and may lead to death. This is because BEVYXXA is a blood thinner medicine that reduces blood clotting. The risk of bleeding is higher in people who have severe kidney problems (severe renal impairment).

You may have a higher risk of bleeding if you take BEVYXXA and 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)
- warfarin sodium (Coumadin®, Jantoven®)
- any medicine that contains heparin
- selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs)
- other medicines to prevent or treat blood clots
- P-glycoprotein (P-gp) inhibitors

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.

While taking BEVYXXA:

- you may bruise more easily
- it may take longer than usual 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 when taking BEVYXXA:

- unexpected bleeding, or bleeding that lasts a long time such as:
 - unusual bleeding from the gums
 - nosebleeds that happen often
 - menstrual bleeding or vaginal bleeding that is heavier than normal
- bleeding that is severe or you cannot control
- red, pink, or brown urine
- red or black stools (looks like tar)
- cough up blood or blood clots
- vomit blood or your vomit looks like coffee grounds
- unexpected pain, swelling, or joint pain
- headaches, feeling dizzy or weak

- **Spinal or epidural blood clots (hematoma).** People who take a blood thinner medicine (anticoagulant) like BEVYXXA, 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:

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

If you take BEVYXXA 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 (especially in your legs and feet), muscle weakness, or loss of control of the bowels or bladder (incontinence).

See “**What are the possible side effects of BEVYXXA?**” for more information about side effects.

What is BEVYXXA?

BEVYXXA is a prescription medicine used to help prevent blood clots in adults who are hospitalized for an acute illness, and are at risk of getting blood clots because of the loss of or decreased ability to move around (mobility) and other risks for getting blood clots.

- It is not known if BEVYXXA is safe and effective in people with artificial heart valves.
- It is not known if BEVYXXA is safe and effective in children.

Do not take BEVYXXA if you:

- have bleeding problems. Tell your healthcare provider if you have, or are at risk for, bleeding problems.
- are allergic to betrixaban or to any of the ingredients in BEVYXXA. See the end of this Medication Guide for a complete list of ingredients in BEVYXXA.

Before taking BEVYXXA, tell your healthcare provider about all your medical conditions, including if you:

- have liver or kidney problems
- have ever had bleeding problems
- have an artificial heart valve
- are pregnant or plan to become pregnant. It is not known if BEVYXXA will harm your unborn baby. Taking BEVYXXA may increase the risk of bleeding during pregnancy and delivery.
- are breastfeeding or plan to breastfeed. It is not known if BEVYXXA passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take BEVYXXA.

Tell all of your healthcare providers and dentists that you are taking BEVYXXA. Talk to the healthcare provider who prescribed BEVYXXA for you, before you have **any** surgery, 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 BEVYXXA works. Certain medicines may increase your risk of bleeding when taken with BEVYXXA. See **“What is the most important information I should know about BEVYXXA?”** and **“What is BEVYXXA?”**

How should I take BEVYXXA?

- **Take BEVYXXA exactly as prescribed by your healthcare provider.**
- Take BEVYXXA 1 time a day with food.
- Your healthcare provider will decide how long you should take BEVYXXA. Do not change your dose or stop taking BEVYXXA unless your healthcare provider tells you to.
- If you miss a dose of BEVYXXA, take it as soon as you remember on the same day. Take your next dose at your usual time the next day. Do not take more than 1 dose of BEVYXXA at the same time to make up for a missed dose.
- If you take too much BEVYXXA, go to the nearest hospital emergency room or call your healthcare provider right away.

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.

What are the possible side effects of BEVYXXA?

BEVYXXA can cause serious side effects.

- See **“What is the most important information I should know about BEVYXXA?”**

The most common side effect of BEVYXXA is bleeding.

These are not all of the side effects of BEVYXXA. 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 BEVYXXA?

- Store BEVYXXA at room temperature between 68°F to 77°F (20°C to 25°C).

Keep BEVYXXA and all medicines out of the reach of children.

General information about the safe and effective use of BEVYXXA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use BEVYXXA for a condition for which it was not prescribed. Do not give BEVYXXA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about BEVYXXA that is written for health professionals.

What are the ingredients in BEVYXXA?

Active ingredient: betrixaban

Inactive ingredients: dextrose monohydrate, croscarmellose sodium, magnesium stearate, and a hard gelatin capsule

Manufactured for: Portola Pharmaceuticals, Inc., South San Francisco, California 94080 USA, Copyright© Portola Pharmaceuticals.

For more information, call 1-866-777-5947 or go to www.BEVYXXA.com

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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