

MEDICATION GUIDE
Apixaban Tablets (a PIX a ban)

What is the most important information I should know about apixaban tablets?

Apixaban tablets may cause serious side effects, including:

- Increased risk of blood clots if you stop taking apixaban tablets.
Apixaban tablets lowers your chance of having a stroke by helping to prevent clots from forming. If you stop taking apixaban tablets, you may have increased risk of forming a clot in your blood.
Do not stop taking apixaban tablets without talking to the healthcare provider who prescribes it for you. Stopping apixaban tablets increases your risk of having a stroke.
Apixaban tablets may need to be stopped, if possible, prior to surgery or a medical or dental procedure. Ask the healthcare provider who prescribed apixaban tablets for you when you should stop taking it. Your healthcare provider will tell you when you may start taking apixaban tablets again after your surgery or procedure. If you have to stop taking apixaban tablets, your healthcare provider may prescribe another medicine to help prevent a blood clot from forming.

- Increased risk of bleeding. apixaban tablets can cause bleeding which can be serious and may lead to death. This is because apixaban tablets are a blood thinner medicine that reduces blood clotting.
You may have a higher risk of bleeding if you take apixaban tablets and take other medicines that increase your risk of bleeding, including:
 - aspirin or aspirin-containing products
 - long-term (chronic) use of nonsteroidal anti-inflammatory drugs (NSAIDs)
 - warfarin sodium
 - any medicine that contains heparin
 - clopidogrel
 - selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs)
 - other medicines to help prevent or treat blood clots

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.

During treatment with apixaban tablets:

- 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 or your child develop any of these signs or symptoms of bleeding during treatment with apixaban tablets:

- unexpected bleeding or bruising, 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 apixaban tablets, 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 apixaban tablets and receive spinal anesthesia or have a spinal puncture, your healthcare provider should watch you closely for symptoms of spinal or epidural blood clots or bleeding. Tell your healthcare provider or get medical help right away if you have back pain, tingling, numbness, or muscle weakness, especially in your legs and feet, or loss of control of the bowels or bladder (incontinence).

- Apixaban tablets are not for use in people with artificial heart valves.
- Apixaban tablets are not for use in people with antiphospholipid syndrome (APS), especially with positive triple antibody testing.

What is Apixaban Tablets?

Apixaban tablets is a prescription medicine used in adults to:

- reduce the risk of stroke and blood clots in people who have atrial fibrillation (a type of irregular heartbeat) that is not caused by a heart valve problem.
- help prevent a blood clot in the veins of your legs (deep vein thrombosis or DVT) and lungs (pulmonary embolism or PE) of people who have just had hip or knee replacement surgery.
- treat deep vein thrombosis (DVT) or pulmonary embolism (PE)
- reduce the risk of DVT or PE from happening again after receiving treatment for blood clots.

Apixaban tablets are used in children from birth and older to treat blood clots in the veins of your legs and lungs (venous thromboembolism) after at least 5 days of initial anticoagulant treatment, and to reduce the risk of them happening again.

Apixaban tablets was not studied and is not recommended in children who weigh less than 5.7 pounds (2.6 kg).

Do not take Apixaban tablets if you or your child:

- currently have certain types of abnormal bleeding.
- have had a severe allergic reaction to apixaban or any of the ingredients in apixaban tablets. Ask your healthcare provider if you are not sure. See the end of this Medication Guide for a complete list of ingredients in apixaban tablets.

Before taking apixaban tablets, tell your healthcare provider about all of your medical conditions, including if you or your child:

- have or ever had bleeding problems
- have kidney or liver problems
- have antiphospholipid syndrome (APS)
- are pregnant or plan to become pregnant. It is not known if apixaban tablets will harm your unborn baby.
 - Tell your healthcare provider** right away if you become pregnant during treatment with apixaban tablets. Taking apixaban tablets during pregnancy may increase the risk of bleeding in you or in your unborn baby.
 - Females who are able to become pregnant:** Talk with your healthcare provider about pregnancy planning during treatment with apixaban tablets. Talk

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with your healthcare provider about your risk for severe uterine bleeding if you are treated with apixaban tablets.

- If you take apixaban tablets during pregnancy, tell your healthcare provider right away if you develop any signs or symptoms of bleeding or blood loss. See **“What is the most important information I should know about apixaban tablets?” for signs and symptoms of bleeding.**
- are breastfeeding or plan to breastfeed. It is not known if apixaban tablets passes into your breast milk. Do not breastfeed during treatment with apixaban tablets. Talk to your healthcare provider about the best way to feed your baby during treatment with apixaban tablets.

Tell all of your healthcare providers and dentists that you or your child are taking apixaban tablets. They should talk to the healthcare provider who prescribed apixaban tablets for you, before you have **any** surgery, medical or dental procedure.

Tell your healthcare provider about all the medicines you or your child take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some of your other medicines may affect the way apixaban tablets works, causing side effects. Certain medicines may increase your risk of bleeding or stroke when taken with apixaban tablets. See **“What is the most important information I should know about apixaban tablets?”**

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

How should I take apixaban tablets?

- **Take apixaban tablets exactly as prescribed by your healthcare provider.**
- Take apixaban tablets 2 times every day.
- Do not change your dose or stop taking apixaban tablets unless your healthcare provider tells you to.
- If you or your child misses a dose of apixaban tablets, take it as soon as you remember on the same day. Do not take 2 doses of apixaban tablets at the same time to make up for a missed dose. Return to your usual dosing schedule the next day.
- For adults and children weighing at least 77 pounds (35 kg), if you have trouble swallowing the tablet whole, talk to your healthcare provider about other ways to take apixaban tablets tablets.
- Your healthcare provider will decide how long you should take apixaban tablets. **Do not stop taking it without first talking with your healthcare provider.**
- **Do not run out of apixaban tablets. Refill your prescription before you run out.** When leaving the hospital following hip or knee replacement, be sure that you will have apixaban tablets available to avoid missing any doses.
- If you take too much apixaban tablets, call your healthcare provider or go to the nearest hospital emergency room right away.
- Call your healthcare provider or healthcare provider right away if you fall or injure yourself, especially if you hit your head. Your healthcare provider or healthcare provider may need to check you.

For children who take apixaban tablets:

- **See the detailed Instructions for Use that comes with apixaban tablets SPRINKLE for oral suspension or apixaban tablets tablets for oral suspension for information on how to prepare and give a dose of apixaban tablets** to children who weigh less than 77 pounds (35 kg).
- Always give apixaban tablets exactly as your child's healthcare provider or pharmacist has told you.
- The dose of apixaban tablets are based on your child's body weight. Your child's healthcare provider may need

to change your child's dose as their weight changes. Do not change your child's dose without talking with the healthcare provider.

- If a child vomits or spits up within 30 minutes after taking apixaban tablets, repeat the dose. If a child vomits or spits up more than 30 minutes after taking apixaban tablets, do not repeat the dose. Continue to give the next apixaban tablets dose at the next scheduled time.
- Contact the healthcare provider if your child repeatedly vomits or spits up after taking apixaban tablets.

What are the possible side effects of apixaban tablets?

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

The most common side effect of apixaban tablets in adults was bleeding.

The most common side effect of apixaban tablets in children include:

- headache
- heavy menstrual bleeding
- vomiting

These are not all of the possible side effects of apixaban tablets.

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 apixaban tablets?

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

Keep apixaban tablets and all medicines out of the reach of children.

General Information about apixaban tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use apixaban tablets for a condition for which it was not prescribed. Do not give apixaban tablets 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 apixaban tablets that is written for health professionals.

What are the ingredients in apixaban tablets?

Active ingredient: apixaban

Inactive ingredients: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone and sodium lauryl sulfate. The film coating contains hypromellose, titanium dioxide, triacetin, and yellow iron oxide (2.5 mg tablets) or red iron oxide (5 mg tablets).

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



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