**THERE'S MORE TO KNOW™** 



# Diagnosed with DVT/PE blood clots? Your journey with XARELTO® starts here.

### **Select Important Safety Information**

Do not stop taking XARELTO<sup>®</sup> without talking to the doctor who prescribes it for you. Stopping XARELTO<sup>®</sup> increases your risk of having a stroke.

Please read additional Important Safety Information on pages 20-23. Please read full Prescribing Information, including Boxed Warnings, and Medication Guide for XARELTO<sup>®</sup>, in pocket.



### Welcome

You were diagnosed with a DVT or PE. Now you ask yourself: "What's next?" You wonder if it could happen again, and what caused it in the first place. But most importantly, you want to understand how you can help protect yourself from another event.

As you embark on your treatment and recovery with XARELTO<sup>®</sup>, we want you to know that we have resources to help you start and stay on track. Along with the discussions you've already had with your healthcare provider, we want to give you information and tools to move ahead.

# Let's get started.

#### **Select Important Safety Information**

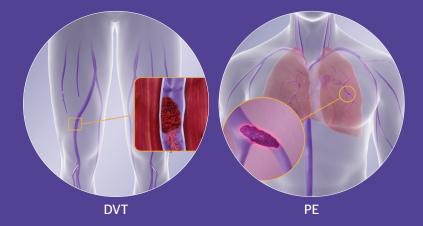
**Increased risk of bleeding.** XARELTO<sup>®</sup> can cause bleeding which can be serious, and may lead to death. This is because XARELTO<sup>®</sup> is a blood thinner medicine (anticoagulant) that lowers blood clotting. During treatment with XARELTO<sup>®</sup> you are likely to bruise more easily, and it may take longer for bleeding to stop. You may be at higher risk of bleeding if you take XARELTO<sup>®</sup> and have certain other medical problems.

Call your doctor or get medical help right away if you develop any signs or symptoms of bleeding.

Please read additional Important Safety Information on pages 20-23. Please read full Prescribing Information, including Boxed Warnings, and Medication Guide for XARELTO<sup>®</sup>, in pocket.

# What are DVT and PE blood clots?

A deep vein thrombosis (DVT) is a blood clot that forms in a vein deep inside your body, such as in the legs. DVT is a serious condition and can lead to a pulmonary embolism.



A pulmonary embolism (PE) occurs when a blood clot formed elsewhere in your body travels through the bloodstream and becomes lodged in your lungs. A PE can block blood flow and is potentially life threatening.

# A PE and a DVT are collectively referred to as VTE (venous thromboembolism).

Did you know that DVT and PE cause more deaths in the US than breast cancer, traffic accidents, and HIV combined?

**DVT/PE** 100,000

Breast Cancer. Traffic Accidents. and HIV 82.840

### Select Important Safety Information

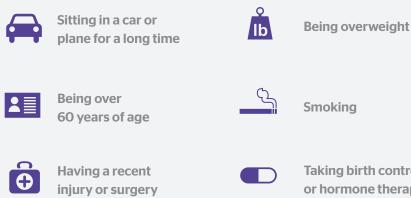
Do not take XARELTO® if you:

- Currently have certain types of abnormal bleeding. Talk to your doctor before taking XARELTO<sup>®</sup> if you currently have unusual bleeding.
- Are allergic to rivaroxaban or any of the ingredients of XARELTO®.

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## What are the risk factors?

Though it is not always possible to pinpoint the exact reason you had a DVT or PE, there are risk factors that contribute to their onset. They include:





Smoking

**Taking birth control pills** or hormone therapy





of DVT or PE





#### Select Important Safety Information

Do not stop taking XARELTO<sup>®</sup> without talking to the doctor who prescribes it for you. Stopping XARELTO<sup>®</sup> increases your risk of having a stroke.

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### What are the symptoms?

### Common symptoms of a DVT include:

Swelling of the leg or affected area

• Pain or tenderness at rest or when standing or walking

• Skin that is warm to the touch

• Skin that is red or discolored

# However, it's important to note that as many as half of the people who get a DVT show no symptoms.

### Common symptoms of a PE include:

- Unexplained shortness of breath
- Rapid breathing
- Chest pain under rib cage that may
   worsen with deep breath
- Coughing or coughing up blood

#### Select Important Safety Information

**Increased risk of bleeding.** XARELTO<sup>®</sup> can cause bleeding which can be serious, and may lead to death. This is because XARELTO<sup>®</sup> is a blood thinner medicine (anticoagulant) that lowers blood clotting. During treatment with XARELTO<sup>®</sup> you are likely to bruise more easily, and it may take longer for bleeding to stop. You may be at higher risk of bleeding if you take XARELTO<sup>®</sup> and have certain other medical problems.

### Why XARELTO<sup>®</sup> may be right for you

If you've already had a DVT or PE, you have an increased risk of developing another blood clot, and your risk increases over time.

### Risk of another DVT or PE after stopping treatment\*

If caused by:	After 1 year	After 5 years
A recent surgery (eg, hip or knee)	1%	3%
A nonsurgical event (eg, pregnancy, leg injury, long flights)	5%	15%
Unknown risk factor	10%	30%

\*In patients with upper-leg DVT or PE after stopping treatment with a blood thinner. Your individual risk may vary, so talk to your doctor.

Treatment with XARELTO® reduces your risk of another DVT or PE blood clot. It's been proven to have similar effectiveness to warfarin, with significantly less major bleeding. XARELTO® works by helping to prevent the formation of blood clots.

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## How do blood thinners work?

# Despite their name, blood thinners do not actually thin the blood.

They work by reducing the formation of blood clots in your arteries or veins. While blood thinners do not dissolve existing clots, they can help prevent clots from becoming larger and causing more serious problems.

### There are 2 main types of blood thinner medicines:

- Anticoagulants, such as XARELTO<sup>®</sup>, help prevent or reduce blood clotting
- Antiplatelet drugs, such as aspirin, help keep platelets (a type of blood cell) from sticking together and forming a clot

# See how XARELTO® compares to warfarin

	XARELTO <sup>®</sup> (rivaroxaban)	Warfarin (eg, Coumadin®)*
How Medication Works	XARELTO <sup>®</sup> works by blocking Factor Xa ("10a"), an enzyme needed for blood clots to form.	Warfarin works by interfering with vitamin K, and at least 6 blood-clotting factors.
Blood Monitoring	<b>No regular blood tests.</b> Regular blood tests are not required with XARELTO <sup>®</sup> .	<b>Requires blood tests.</b> Blood tests are required at the start and throughout your treatment.
Dietary Restrictions	<b>No known dietary</b> <b>restrictions.</b> With XARELTO <sup>®</sup> , you can continue to eat the healthy foods you enjoy.	<b>Dietary restrictions exist.</b> Spinach, cabbage, broccoli, and other foods high in vitamin K can affect how well warfarin works.
Drug Interactions	There are limited known interactions between XARELTO® and other medications. Please talk to your doctor about a list of medications that may interact with XARELTO®.	There is a broad range of medications that interact with warfarin. Please talk to your doctor about a list of medications that may interact with warfarin.

\*Coumadin<sup>®</sup> is a registered trademark of Bristol-Myers Squibb.

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### What is XARELTO®?

XARELTO<sup>®</sup> is a latest-generation blood thinner that's proven to reduce the risk of another DVT and PE.

### In clinical studies, almost 98% of people taking XARELTO<sup>®</sup> did not experience another DVT or PE.\*

\*Patients were followed for an average length of treatment of 208 days.

To benefit from XARELTO<sup>®</sup>, you should take it exactly as your doctor prescribes. Your doctor will decide how long you should take XARELTO<sup>®</sup>. Do not stop taking XARELTO<sup>®</sup> without talking with your doctor first. Stopping XARELTO<sup>®</sup> may increase your risk of stroke.

If you miss a dose of XARELTO<sup>®</sup>, take it as soon as you remember on the same day. Take your next dose at your regularly scheduled time.

Tell all your doctors, including dentists, that you are taking XARELTO<sup>®</sup>. They should talk to the doctor who prescribed XARELTO<sup>®</sup> for you before any surgical, medical, or dental procedure. Your doctor may stop your XARELTO<sup>®</sup> for a short time and tell you when to start taking XARELTO<sup>®</sup> again after your surgery or procedure.

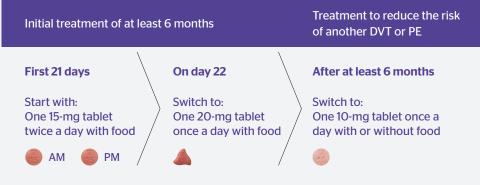
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### **Start your treatment with XARELTO®**

# XARELTO<sup>®</sup> has already been prescribed more than 40 million times in the US, and it is proven to work.

In the largest clinical study of DVT and PE ever conducted, XARELTO<sup>®</sup> was proven effective at treating DVT and PE, and reducing the risk of these blood clots happening again.

For most patients who are prescribed XARELTO<sup>®</sup> for DVT or PE, the dosing schedule is:



Tablets shown not actual size

### Select Important Safety Information Do not take XARELTO® if you:

- Currently have certain types of abnormal bleeding. Talk to your doctor before taking XARELTO® if you currently have unusual bleeding.
- Are allergic to rivaroxaban or any of the ingredients of XARELTO®.

# Use this Dosing Diary to help make your treatment easy to follow

Start with 1 XARELTO® 1 tablet twice a day with f	0	Week 1	l starting //	date:	Schedule	ed times: PM		On day 22, 20-mg tab					5 starting /	) date: /		led time: PM
Check the box below for the dose taken every day.						Check the box below for the dose taken every day.										
Day 1 Day 1 Day 1 Day 1 Day 1 Day 8 Day 8 Day 8 Day 8 Day 8 Day 8 Day 1 Day 1 Day 1 Day 1 Day 1 Day 1	 Day 9	Day 10	Day 4	Day 5	Day 6	Day 7		WEEK 5 WEEK 6 WEEK 7 WEEK 8 WEEK 9		Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Taking all of your medication is important,	even if you're feelin	ug well.			 15-n	ng tablet		WEEK 10 WEEK 11 WEEK 12 WEEK 13								
On day 22, switch to 1 X 20-mg tablet once a day Check the box below for	with food.		starting // lav.	date:		led time: PM		WEEK 14 WEEK 15								
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## **Talking with your doctor**

# Keeping an open and honest conversation going with your doctor will help you get the best care.

At your next appointment, tell your doctor how you're feeling that day and if you are experiencing any DVT or PE symptoms. Here are some questions you may want to ask:

- Can I still be physically active with a DVT or PE?
- Can a DVT or PE lead to a heart attack?
- If I'm no longer feeling any symptoms, does that mean I no longer have to worry?
- How does XARELTO<sup>®</sup> help treat and prevent another DVT or PE?
- What are the benefits and side effects of XARELTO<sup>®</sup> compared to warfarin?
- If there are no regular blood tests or known dietary restrictions, how do I know XARELTO<sup>®</sup> is working?

Am I eligible to save on XARELTO<sup>®</sup> through the Janssen CarePath Savings Program?

## Janssen — Your Partner for Cost Support

At Janssen, we don't want cost to get in the way of treatment you need. We can help you explore options to lower your out-of-pocket cost for XARELTO<sup>®</sup>.

Janssen CarePath offers you valuable information and tools to help you better understand your condition, stay with the treatment plan your doctor prescribes, and save on your XARELTO<sup>®</sup> prescription costs.

- Janssen CarePath Savings Program—See your healthcare provider to learn about how you may be eligible to save on your next XARELTO<sup>®</sup> prescription
- Free Medication Tracker—Keep a record of your medications and a reminder of when to take them
- Ongoing Support–Valuable information to learn more about treating your condition or changing your dose, if necessary
- Helpful Reminders–Reminders on when to refill your prescription
- Dedicated Care Coordinator—A live Care Coordinator can review your insurance coverage for XARELTO<sup>®</sup> and help identify options to help you pay for XARELTO<sup>®</sup>

Signing up is easy. Go to janssencarepath.com/XARELTO or call 1-888-XARELTO (1-888-927-3586).



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# **Frequently Asked Questions**

It is normal to have questions when it comes to your treatment options. You want to make sure you are taking all the steps you can when it comes to protecting your health.

### Q. What makes XARELTO® different?

A. Here's why XARELTO<sup>®</sup> is different: warfarin interferes with vitamin K and at least 6 blood-clotting factors. XARELTO<sup>®</sup> is selective, targeting just one critical factor of your body's natural blood-clotting function. With XARELTO<sup>®</sup>, you don't have to plan your schedule around a blood monitoring routine or change the way you eat.

#### Q. Can I afford XARELTO®, a branded medication?

A. If you have commercial health insurance with prescription coverage, you may be eligible for the Janssen CarePath Savings Program to receive instant savings on your next XARELTO<sup>®</sup> prescription. See your healthcare provider and ask about the Janssen CarePath Savings Program or call 1-888-XARELTO (1-888-927-3586) to enroll or complete activation.

### Q. What is the most important side effect I should be aware of?

A. Like all blood thinners, XARELTO<sup>®</sup> can cause bleeding, which can be serious, and rarely may lead to death. **Be sure to take XARELTO<sup>®</sup> exactly as prescribed and do not stop taking XARELTO<sup>®</sup> without talking with your doctor first. Stopping XARELTO<sup>®</sup> may increase your risk of having a DVT or PE happen again.** You should discuss all potential benefits and risks with your doctor.

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# Q. Are there any foods or medicines I should avoid when taking XARELTO<sup>®</sup>?

A. Unlike warfarin, XARELTO® has no known dietary restrictions. You can eat leafy greens without affecting how XARELTO® works. Like all blood thinners, you have a higher risk of bleeding if you take XARELTO® with other medicines, such as: aspirin, non-steroidal anti-inflammatory drugs (NSAIDs), warfarin, heparin, clopidogrel (Plavix®), selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), or other medicines to prevent or treat blood clots.

### Select Important Safety Information

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

### WHAT IS XARELTO® (rivaroxaban)?

XARELTO<sup>®</sup> is a prescription medicine used to:

- reduce the risk of stroke and blood clots in people 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 the formation of blood clots, which can travel to the brain, causing a stroke, or to other parts of the body
- treat blood clots in the veins of your legs (deep vein thrombosis or DVT) or lungs (pulmonary embolism or PE)
- reduce the risk of blood clots happening again in people who continue to be at risk for DVT or PE after receiving treatment for blood clots for at least 6 months
- help prevent a blood clot in the legs and lungs of people who have just had hip or knee replacement surgery
- help prevent blood clots in certain people hospitalized for an acute illness and after discharge, who 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, and who do not have a high risk of bleeding

XARELTO® is used with low dose aspirin to:

- reduce the risk of serious heart problems, heart attack and stroke in people with coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) or peripheral artery disease (a condition where the blood flow to the legs is reduced)
- It is not known if XARELTO® is safe and effective in children.

### **IMPORTANT SAFETY INFORMATION**

#### WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT XARELTO®?

#### XARELTO® may cause serious side effects, including:

• Increased risk of blood clots if you stop taking XARELTO®. People with atrial fibrillation (an irregular heart beat) that is not caused by a heart valve problem (nonvalvular) 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. XARELTO® lowers your chance of having a stroke by helping to prevent clots from forming. If you stop taking XARELTO®, you may have increased risk of forming a clot in your blood.

### **Do not stop taking XARELTO® without talking to the doctor who prescribes it for you. Stopping XARELTO® increases your risk of having a stroke.** If you have to stop taking XARELTO®, your doctor may prescribe another blood thinner medicine to prevent a blood clot from forming.

 Increased risk of bleeding. XARELTO<sup>®</sup> can cause bleeding which can be serious, and may lead to death. This is because XARELTO<sup>®</sup> is a blood thinner medicine (anticoagulant) that lowers blood clotting. During treatment with XARELTO<sup>®</sup> you are likely to bruise more easily, and it may take longer for bleeding to stop. You may be at higher risk of bleeding if you take XARELTO<sup>®</sup> and have certain other medical problems.

### You may have a higher risk of bleeding if you take XARELTO<sup>®</sup> and take other medicines that increase your risk of bleeding, including:

- Aspirin or aspirin-containing products
- $\circ$  Long-term (chronic) use of non-steroidal anti-inflammatory drugs (NSAIDs)
- Warfarin sodium (Coumadin<sup>®</sup>, Jantoven<sup>®</sup>)
- Any medicine that contains heparin
- Clopidogrel (Plavix<sup>®</sup>)
- Selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs)
- Other medicines to prevent or treat blood clots

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

### Call your doctor or get medical help right away if you develop any of these signs or symptoms of bleeding:

- $\circ$  Unexpected bleeding or bleeding that lasts a long time, such as:
- Nosebleeds that happen often
- Unusual bleeding from gums
- Menstrual bleeding that is heavier than normal, or vaginal bleeding
- $\circ$  Bleeding that is severe or you cannot control
- $\circ$  Red, pink, or brown urine

- $\circ$  Bright red or black stools (looks like tar)
- $\circ$  Cough up blood or blood clots
- Vomit blood or your vomit looks like "coffee grounds"
- $\circ$  Headaches, feeling dizzy or weak
- Pain, swelling, or new drainage at wound sites

• Spinal or epidural blood clots (hematoma). People who take a blood thinner medicine (anticoagulant) like XARELTO<sup>®</sup>, 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:

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

If you take XARELTO<sup>®</sup> and receive spinal anesthesia or have a spinal puncture, your doctor should watch you closely for symptoms of spinal or epidural blood clots. Tell your doctor right away if you have back pain, tingling, numbness, muscle weakness (especially in your legs and feet), or loss of control of the bowels or bladder (incontinence).

XARELTO® is not for use in people with artificial heart valves.

XARELTO<sup>®</sup> is not for use in people with antiphospholipid syndrome (APS), especially with positive triple antibody testing.

### Do not take XARELTO® if you:

- Currently have certain types of abnormal bleeding. Talk to your doctor before taking XARELTO<sup>®</sup> if you currently have unusual bleeding.
- Are allergic to rivaroxaban or any of the ingredients of XARELTO®.

### Before taking XARELTO®, tell your doctor about all your medical conditions, including if you:

- Have ever had bleeding problems
- Have liver or kidney problems
- Have antiphospholipid syndrome (APS)
- Are pregnant or plan to become pregnant. It is not known if XARELTO<sup>®</sup> will harm your unborn baby.
- Tell your doctor right away if you become pregnant during treatment with XARELTO<sup>®</sup>. Taking XARELTO<sup>®</sup> while you are pregnant may increase the risk of bleeding in you or in your unborn baby.
- If you take XARELTO<sup>®</sup> during pregnancy, tell your doctor right away if you have any signs or symptoms of bleeding or blood loss. See "What is the most important information I should know about XARELTO<sup>®</sup>?" for signs and symptoms of bleeding.
- Are breastfeeding or plan to breastfeed. XARELTO® may pass into your breast milk. Talk to your doctor about the best way to feed your baby during treatment with XARELTO®.

Tell all of your doctors and dentists that you are taking XARELTO<sup>®</sup>. They should talk to the doctor who prescribed XARELTO<sup>®</sup> for you before you have any surgery, medical or dental procedure.

Please read full Prescribing Information, including Boxed Warnings, and Medication Guide for XARELTO<sup>®</sup>, in pocket.

### IMPORTANT SAFETY INFORMATION (cont'd)

Tell your doctor 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 XARELTO<sup>®</sup> works, causing side effects. Certain medicines may increase your risk of bleeding. **See "What is the most important information I should know about XARELTO**<sup>®</sup>**?**"

### **HOW SHOULD I TAKE XARELTO®?**

- Take XARELTO<sup>®</sup> exactly as prescribed by your doctor.
- Do not change your dose or stop taking XARELTO<sup>®</sup> unless your doctor tells you to. Your doctor may change your dose if needed.
- Your doctor will decide how long you should take XARELTO®.
- XARELTO<sup>®</sup> may need to be stopped for one or more days before any surgery or medical or dental procedure. Your doctor will tell you when to stop taking XARELTO<sup>®</sup> and when to start taking XARELTO<sup>®</sup> again after your surgery or procedure.
- If you need to stop taking XARELTO<sup>®</sup> for any reason, talk to the doctor who prescribed XARELTO<sup>®</sup> to you to find out when you should stop taking it. Do not stop taking XARELTO<sup>®</sup> without first talking to the doctor who prescribes it to you.
- If you have difficulty swallowing XARELTO<sup>®</sup> tablets whole, talk to your doctor about other ways to take XARELTO<sup>®</sup>.
- Do not run out of XARELTO<sup>®</sup>. Refill your prescription of XARELTO<sup>®</sup> before you run out. When leaving the hospital following a hip or knee replacement, be sure that you will have XARELTO<sup>®</sup> available to avoid missing any doses.
- If you take too much XARELTO<sup>®</sup>, go to the nearest hospital emergency room or call your doctor right away.

### If you take XARELTO<sup>®</sup> for:

- Atrial Fibrillation that is not caused by a heart valve problem:
  - Take XARELTO® 1 time a day with your evening meal.
  - If you miss a dose of XARELTO<sup>®</sup>, take it as soon as you remember on the same day. Take your next dose at your regularly scheduled time.
- $\circ\,$  Blood clots in the veins of your legs or lungs:
  - Take XARELTO® **1 or 2 times a day** as prescribed by your doctor.
  - For the 10-mg dose, XARELTO® may be taken with or without food.
- For the **15-mg and 20-mg doses**, take XARELTO® with food at the same time each day.
- If you miss a dose:
- If you take the 15-mg dose of XARELTO® 2 times a day (a total of 30 mg of XARELTO® in 1 day): Take XARELTO® as soon as you remember on the same day. You may take 2 doses at the same time to make up for the missed dose. Take your next dose at your regularly scheduled time.
- > If you take XARELTO® 1 time a day: Take XARELTO® as soon as you remember on the same day. Take your next dose at your regularly scheduled time.

### $\circ~$ Hip or knee replacement surgery:

- Take XARELTO® 1 time a day with or without food.
- If you miss a dose of XARELTO<sup>®</sup>, take it as soon as you remember on the same day. Take your next dose at your regularly scheduled time.

- <sup>°</sup> Blood clots in people hospitalized for an acute illness:
  - Take XARELTO<sup>®</sup> 1 time a day, with or without food, while you are in the hospital and after you are discharged as prescribed by your doctor.
- If you miss a dose of XARELTO<sup>®</sup>, take it as soon as you remember on the same day. Take your next dose at your regularly scheduled time.
- Reducing the risk of serious heart problems, heart attack and stroke in coronary artery disease or peripheral artery disease:
  - Take XARELTO<sup>®</sup> 2.5 mg 2 times a day with or without food.
  - If you miss a dose of XARELTO<sup>®</sup>, take your next dose at your regularly scheduled time.
- Take aspirin 75 to 100 mg once daily as instructed by your doctor.

#### WHAT ARE THE POSSIBLE SIDE EFFECTS OF XARELTO®?

XARELTO® may cause serious side effects:

See "What is the most important information I should know about XARELTO"?"

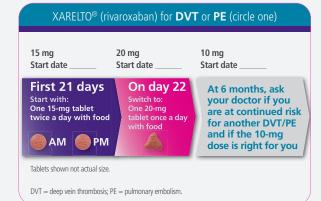
The most common side effect of XARELTO® was bleeding.

Call your doctor for medical advice about side effects. **You may report side effects to the FDA at 1-800-FDA-1088.** You may also report side effects to Janssen Pharmaceuticals, Inc., at 1-800-JANSSEN (1-800-526-7736).

# Please read full Prescribing Information, including Boxed Warnings, and Medication Guide for XARELTO<sup>®</sup>, in pocket.

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Detach this wallet card and complete both sides to help you remember your dosing schedule. Keep it with you in case of an emergency.



# cp-53637v6

We hope this brochure has been helpful in answering your questions and guiding you on your journey with XARELTO<sup>®</sup>.

# Please feel free to visit us at XARELTO.com or by calling 1-888-XARELTO (1-888-927-3586).

Please read accompanying full Prescribing Information for XARELTO<sup>®</sup>, including Boxed Warnings, and Medication Guide, and Important Safety Information.

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