

## What is XARELTO® (rivaroxaban)?

XARELTO® is a **latest-generation anticoagulant**, or **blood thinner**, that works by blocking Factor Xa ("10a"), an enzyme needed for blood clots to form.

## What does XARELTO® treat?

XARELTO® is approved for six indications in the U.S. that include:

### Atrial Fibrillation

Significantly lowers **the risk of stroke** in people with non-valvular atrial fibrillation.



### DVT & PE

Treats and helps to **prevent deep vein thrombosis and pulmonary embolism**.



### Hip and Knee

**Reduces the risk of forming a blood clot** after hip or knee replacement.



## How is XARELTO® different from warfarin?

- Warfarin, an older anticoagulant requiring dietary restrictions and blood monitoring, interferes with vitamin K and at least six blood-clotting factors. XARELTO® **targets one critical factor** of your body's natural clotting function and has similar effectiveness to warfarin.

With XARELTO®, there is:

- No** regular blood monitoring
- No** frequent dosing adjustments
- No** known dietary restrictions

## Value and Access

- #1** XARELTO® leads the **non-vitamin K antagonist oral anticoagulant (NOAC) class** with the largest clinical research program and the strongest access position with class-leading coverage, providing the lowest out-of-pocket cost to patients in the U.S.



For patients with commercial health insurance with prescription coverage, the **Janssen CarePath savings card** helps patients access XARELTO® with a **\$0 co-pay** every month.\*



XARELTO® is the **only NOAC** covered by **CVS Caremark Managed Medicaid** and is **preferred** over other NOACs by **CVS SilverScript, Cigna HealthSpring and Aetna Medicare Part D Plans**.



XARELTO® has preferred coverage for more than **95 percent** of commercial & Medicare Part D patients at the lowest branded co-pay.



**More than 25 million prescriptions** have been written for XARELTO® in the U.S. since its launch in 2011.

## Real-world findings



**More than 196,000 people** have been evaluated in published real-world research\*\* since the approval of XARELTO® **across all six indications in the United States**.



## Ongoing Clinical Research

- The EXPLORER program is unmatched by any oral anticoagulant in the NOAC class in its size, scope and ambition. A collaborative effort between Bayer and Janssen, EXPLORER seeks to **generate important clinical evidence on the safety and efficacy of XARELTO® and its potential role in addressing critical unmet medical needs**.
- By the time of its completion, **more than 275,000 patients** will have participated in the EXPLORER clinical development program, other completed and ongoing clinical trials, investigative registries and non-interventional studies.
- A number of the studies are designed to seek additional indications or expand the label for XARELTO®.

## INDICATIONS:

### WHAT IS XARELTO®?

XARELTO® is a prescription medicine used to reduce the risk of stroke and blood clots in people with atrial fibrillation, not caused by a heart valve problem. For patients currently well managed on warfarin, there is limited information on how XARELTO® and warfarin compare in reducing the risk of stroke.

XARELTO® is also a prescription medicine used to treat deep vein thrombosis and pulmonary embolism, and to help reduce the risk of these conditions occurring again.

XARELTO® is also a prescription medicine used to reduce the risk of forming a blood clot in the legs and lungs of people who have just had knee or hip replacement surgery.

## IMPORTANT SAFETY INFORMATION:

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

- For people taking XARELTO® for atrial fibrillation:**

People with atrial fibrillation (an irregular heart beat) 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.

\* Subject to a maximum annual program benefit of \$3,400.

\*\* Based on the following registries, claims, and studies across all 6 indications: Optum Labs data=16,253; IMS Health information=1,649; Truven Health Analytics/Medicare supplement=5,563; Truven Health Marketscan database=7,259; Danish registry=1,303; XANTUS=6,784; Health ResearchTx/US DoD=39,052; Dresden NOAC registry=1,776; Japanese registry=1,035; ORTHO-TEP registry=1,043; Symphony claims=3,654; Humana claims=2,253; XAMOS=8,778; XALIA=2,619; XAPASS=9,101.

## IMPORTANT SAFETY INFORMATION (cont'd)

**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.

- **XARELTO® can cause bleeding**, which can be serious, and rarely may lead to death. This is because XARELTO® is a blood thinner medicine that reduces blood clotting. While you take XARELTO® you are likely to bruise more easily and it may take longer for bleeding to stop.

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

- Aspirin or aspirin-containing products
- Non-steroidal anti-inflammatory drugs (NSAIDs)
- Warfarin sodium (Coumadin®, Jantoven®)
- Any medicine that contains heparin
- Clopidogrel (Plavix®)
- 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:**

- 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
- Bleeding that is severe or that you cannot control
- Red, pink, or brown urine
- Bright red or black stools (looks like tar)
- Cough up blood or blood clots
- Vomit blood or your vomit looks like “coffee grounds”
- 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®, 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 XARELTO® 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 patients with artificial heart valves.**

### WHO SHOULD NOT TAKE XARELTO®?

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®.

### WHAT SHOULD I TELL MY DOCTOR BEFORE OR WHILE TAKING XARELTO®?

Before taking XARELTO®, tell your doctor if you:

- Have ever had bleeding problems
- Have liver or kidney problems
- Have any other medical condition
- Are pregnant or plan to become pregnant. It is not known if XARELTO® will harm your unborn baby. Tell your doctor right away if you become pregnant while taking XARELTO®. If you take XARELTO® during pregnancy, tell your doctor right away if you have bleeding or symptoms of blood loss.
- Are breastfeeding or plan to breastfeed. It is not known if XARELTO® passes into your breast milk. You and your doctor should decide if you will take XARELTO® or breastfeed.

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

**Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.** Some of your other medicines may affect the way XARELTO® works. Certain medicines may increase your risk of bleeding. **See “What is the most important information I should know about XARELTO®?”**

## IMPORTANT SAFETY INFORMATION (cont'd)

Especially tell your doctor if you take:

- Ketoconazole (Nizoral®)
- Itraconazole (Onmel™, Sporanox®)
- Ritonavir (Norvir®)
- Lopinavir/ritonavir (Kaletra®)
- Indinavir (Crixivan®)
- Carbamazepine (Carbatrol®, Equetro®, Tegretol®, Tegretol®-XR, Teril™, Epitol®)
- Phenytoin (Dilantin-125®, Dilantin®)
- Phenobarbital (Solfoton™)
- Rifampin (Rifater®, Rifamate®, Rimactane®, Rifadin®)
- St. John's wort (*Hypericum perforatum*)

Ask your doctor if you are not sure if your medicine is one listed above. Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

### HOW SHOULD I TAKE XARELTO®?

Take XARELTO® exactly as prescribed by your doctor.

**Do not change your dose or stop taking XARELTO® unless your doctor tells you to.**

- Your doctor will tell you how much XARELTO® to take and when to take it.
- Your doctor may change your dose if needed.

If you take XARELTO® for:

- o **Atrial Fibrillation:** Take XARELTO® 1 time a day with your evening meal. If you miss a dose of XARELTO®, take it as soon as you remember on the same day. Take your next dose at your regularly scheduled time.
- o **Blood clots in the veins of your legs or lungs:**
  - Take XARELTO® once or twice a day as prescribed by your doctor.
  - Take XARELTO® with food at the same time each day.
  - If you miss a dose of XARELTO®:
    - **and take XARELTO® 2 times a 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.
    - **and 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.

- o **Hip or knee replacement surgery:** Take XARELTO® 1 time a day with or without food. If you miss a dose of XARELTO®, take it as soon as you remember on the same day. Take your next dose at your regularly scheduled time.

- If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take XARELTO®.
- Your doctor will decide how long you should take XARELTO®. Do not stop taking XARELTO® without talking to your doctor first.
- Your doctor may stop XARELTO® for a short time before any surgery, medical or dental procedure. Your doctor will tell you when to start taking XARELTO® again after your surgery or procedure.
- Do not run out of XARELTO®. Refill your prescription for XARELTO® before you run out. When leaving the hospital following a hip or knee replacement, be sure that you have XARELTO® available to avoid missing any doses.
- If you take too much XARELTO®, go to the nearest hospital emergency room or call your doctor right away.

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

*Please see "What is the most important information I should know about XARELTO®?"*

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

**Call your doctor for medical advice about side effects. You are also encouraged to report side effects to the FDA: visit <http://www.fda.gov/medwatch> or call 1-800-FDA-1088.** You may also report side effects to Janssen Pharmaceuticals, Inc., at 1-800-JANSSEN (1-800-526-7736).

Please [click here](#) for full Prescribing Information, including Boxed Warnings, and Medication Guide.

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