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FDA Mini-Sentinel Assessment Confirms Safety and Effectiveness of XARELTO® (rivaroxaban) and its Association with a Lower Risk of Ischemic Stroke vs. Warfarin

XARELTO® remains the most studied oral Factor Xa inhibitor in the world today with more than five million U.S. patients

TITUSVILLE, NJ, January 16, 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced findings from the U.S. Food and Drug Administration’s (FDA) Mini-Sentinel assessment, confirming the positive safety and efficacy profile of XARELTO® (rivaroxaban) established in the phase III ROCKET AF clinical trials, were published in [Pharmacoepidemiology & Drug Safety](#). Building on the mounting real-world evidence studied in more than 200,000 people, these findings are consistent with conclusions from other analyses and again confirm XARELTO®’s safety and effectiveness across a wide range of patients. The FDA Mini-Sentinel report also notes a lower risk of ischemic stroke was associated with the use of XARELTO® compared to

warfarin and lasted throughout the more than three-year analysis.

The [Sentinel Initiative](#) began in 2008 as a multi-year effort to create a national electronic system for monitoring the safety of approved and FDA-regulated medical products using existing electronic healthcare data from multiple sources. The Initiative is FDA's response to the [Food and Drug Administration Amendments Act \(FDAAA\)](#), and includes the Mini-Sentinel, a working pilot project to develop an active surveillance system and complement existing methods of safety surveillance.

"We're pleased to see the Sentinel Initiative in action and that FDA's findings are consistent with results from other independent real-world and post-marketing studies," said Paul Burton, MD, PhD, FACC, Vice President, Medical Affairs, Janssen Pharmaceuticals, Inc. "These FDA results yet again confirm the positive benefit-risk profile of XARELTO® across a wide range of patients."

This FDA analysis evaluated the safety of XARELTO® in people with nonvalvular atrial fibrillation (AF) who initiated XARELTO® or warfarin from November 2011 to April 2015. To examine the safety of both products, methodologies included assessing ICD-9-CM codes from inpatient claims and evaluating rates of gastrointestinal (GI) bleeding, ischemic stroke and intracranial hemorrhage in patients with AF.

In its report, FDA concludes this study, "demonstrates the capability of Sentinel to conduct prospective safety monitoring with sophisticated re-usable tools and does not raise any new safety concerns regarding use of rivaroxaban."

Nearly six million Americans are diagnosed with AF, an irregular heartbeat that can lead to blood clots, stroke, heart failure and other heart-related complications. It is the most common serious heart rhythm abnormality in people over the age of 65. When a clot forms in the heart due to AF, it can travel to the brain and cause a stroke.

[Click to Tweet](#): #FDA report confirms safety and effectiveness of XARELTO® (rivaroxaban). See full PI including BOXED WARNINGS <https://ctt.ec/4P4uC+>

WHAT IS XARELTO®?

XARELTO® (rivaroxaban) 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 (DVT) and pulmonary embolism (PE), and to 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.

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® (rivaroxaban)?

- **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.

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 (anticoagulant) 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 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 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 people with artificial heart valves.**

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[®].

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

- Have ever had bleeding problems
- Have liver or kidney problems
- 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 during treatment with XARELTO®. Taking XARELTO® while you are pregnant may increase the risk of bleeding in you or in your unborn baby.
- If you take XARELTO® 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®?” for signs and symptoms of bleeding.**
- Are breastfeeding or plan to breastfeed. XARELTO® may pass 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 over-the-counter 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®?”**

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 may change your dose if needed.
- If you take XARELTO® for:
 - **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.
 - **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 **15-mg and 20-mg doses**, XARELTO® **should be taken with food.**
 - For the **10-mg dose**, XARELTO® **may be taken with or without food.**
 - Take your XARELTO® dose(s) 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.
 - **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 XARELTO® tablet whole, talk to your doctor about other ways to take XARELTO®.

- Your doctor will decide how long you should take XARELTO®.
- 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®?

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

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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About the Janssen Pharmaceutical Companies

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science.

We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com. Follow us on Twitter at [@JanssenUS](https://twitter.com/JanssenUS). Janssen Pharmaceuticals, Inc. is part of the Janssen Pharmaceutical Companies.

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