

XARELTO® (rivaroxaban)

What Are the Possible Side Effects of XARELTO?

Serious Side Effects of XARELTO



Blood clot formation/stroke if XARELTO is discontinued prematurely



Serious/life-threatening bleeding



Spinal or epidural blood clots leading to loss of the ability to move or cannot move



Increased risk of blood clots and stroke if you stop taking XARELTO

XARELTO helps to prevent clot formation and lowers your risk of stroke.

Stopping XARELTO increases your risk of forming blood clots and having a stroke.



- People with atrial fibrillation (an **irregular heart beat not caused by a heart valve problem**) have a higher risk of forming blood clots in the heart, which can travel to the brain, causing a **stroke**, or to other parts of the body.



- Talk to your doctor before discontinuing XARELTO.
- If you have to stop taking XARELTO, **your doctor may prescribe another blood thinner medicine.**

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Increased risk of bleeding

XARELTO is a blood thinner medicine that lowers blood clotting.

XARELTO may cause serious bleeding that may lead to death.

During treatment with 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 have **certain other medical problems or take other medicines with XARELTO**, like:

| | | |
|---|--|--|
| Aspirin or aspirin-containing products | Nonsteroidal anti-inflammatory drugs for long-term use | Selective serotonin reuptake inhibitors (SSRI) |
| Serotonin norepinephrine reuptake inhibitors (SNRI) | Clopidogrel (Plavix®) | Warfarin sodium (Coumadin®, Jantoven®) |
| Medicines containing heparin | 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 or your child develop the following signs/symptoms:

Unexpected or prolonged bleeding from the nose, gums, or vagina or heavier than normal menstrual bleeding

Severe or uncontrollable bleeding

Red, pink, or brown urine

Bright red or black stools (like tar)

Cough up blood or blood clots

Vomit blood or vomit looking like "coffee grounds"

Headaches, feeling dizzy or weak

Pain, swelling, or new drainage at wound sites

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Spinal or epidural blood clots (hematoma)

XARELTO is a blood thinner medicine that lowers blood clotting.

A spinal/epidural injection or a spinal puncture while on XARELTO may increase the risk of blood clots causing long-term/permanent loss of the ability to move (paralysis).



- The risk of developing a spinal or epidural blood clot is higher with

Placement of a thin tube called an epidural catheter in your back that administers medicine

History of difficult or repeated epidural or spinal punctures

History of spinal problems or spinal surgery

Use of medicines to prevent blood clots

Use of nonsteroidal anti-inflammatory drugs



- If you take XARELTO and receive spinal anesthesia or a spinal puncture, **your doctor should monitor you for spinal or epidural blood clots.**
- Tell your doctor right away if you have:**

Backpain

Loss of control of the bowels or bladder (incontinence)

Tingling

Muscle weakness (especially in your legs and feet)

Numbness

Most Common Side Effects of XARELTO

Adults



Bleeding

Children



Bleeding



Vomiting



Cough



Inflamed stomach and gut

This information is provided ONLY in response to your request and is not intended as medical advice, to promote the use of our product, or suggest using it in any manner other than as described in the PRESCRIBING INFORMATION. All decisions regarding your medical treatment should be made with your healthcare professional(s). Please contact your healthcare professional(s) to discuss the information in this response.

Please refer to the attached full PRESCRIBING INFORMATION and the MEDICATION GUIDE for XARELTO.¹

1. XARELTO (rivaroxaban) [Package Insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc;

<https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/XARELTO-pi.pdf>