

ULCERATIVE COLITIS

TERMS TO KNOW

Speaking up and being heard

If the medical terminology you hear during your gastroenterologist appointments sounds like a foreign language, you are not alone.

These definitions will help you understand some of the things that may be happening in your body so you can have informed conversations with your gastroenterologist about your treatment options and goals.

Ulcerative colitis (UC)

One of two inflammatory bowel diseases (IBD) characterized by chronic inflammation. With UC, the buildup of inflammation occurs in the colon, which can cause colon damage and UC symptoms.

- When you have UC, chronic inflammation can be present even when you are not experiencing UC symptoms. Chronic inflammation can be controlled with treatment options that work for you.

Understanding UC

Autoimmune disease

A chronic condition where the immune system mistakenly attacks healthy cells

Colon

An organ in the digestive system that absorbs water and other elements from partially digested food to form stools that are passed out of the body. The colon is also known as the large intestine

Colon damage

The presence of blood, erosions, and/or ulcers in the colon, caused by excess inflammation

Flare-ups

A period when someone with UC experiences symptoms. The buildup of inflammation that damages the colon is one factor that can contribute to flare-ups

Immune system

The body's system of fighting off invaders that can make someone sick

Inflammation

Your immune system's natural defense to harm, such as redness or swelling. When you have UC, your immune system can cause chronic inflammation, contributing to colon damage and UC symptoms

Inflammatory bowel disease (IBD)

A family of diseases that involve chronic inflammation of the digestive tract. The two types of IBD are ulcerative colitis and Crohn's disease. IBD is not the same thing as irritable bowel syndrome (IBS), which can have similar symptoms but does not involve chronic inflammation

Remission

A period when someone experiences few or no UC symptoms and their colon lining has visibly improved. Your gastroenterologist can confirm if you're in remission based on the frequency of your bowel movements, a lack of bloody stools, and a visible improvement of the colon lining seen in endoscopy results. Consider treatment options that offer lasting remission, even at 1 year

Severity

As a general term, severity refers to how UC affects you, including your measurable symptoms and their potential impact on your ability to complete errands or socialize. This is in addition to your gastroenterologist confirming that you have "moderate to severe UC," which is based on your stool frequency and the presence of blood in your stools

Ulcer

An open sore and a common characteristic of UC, in which ulcers happen in the lining of the colon

Diagnosing and treating UC

Biologics

A substance that is made from a living organism or its products and is given by infusion or injection for the prevention or treatment of various diseases. Biologics are also called biologic agents

Biopsy

A medical procedure where a piece of tissue from the body, such as the colon, is collected and examined in a laboratory. Biopsies can be taken during an endoscopy to check for inflammation or damage to the colon that is visible only with a microscope

Colectomy

A type of surgery that removes part or all of the colon

Endoscopy

A procedure where a flexible tube-like instrument with a light and lens for viewing is used to look at the inside of the digestive tract by entering through the mouth or anus. Endoscopy is used to both diagnose UC and to monitor your disease and potential complications

Gastroenterologist

A doctor who specializes in issues of the gastrointestinal tract, including inflammatory bowel diseases (IBD) like UC

Janus kinase (JAK) inhibitor

Medications that work by targeting some of the proteins involved in inflammation, known as JAK. RINVOQ (upadacitinib) is a JAK inhibitor taken orally as a once-daily pill

Mayo score

A score that looks at four categories (stool frequency, rectal bleeding, endoscopy, and an assessment by your healthcare provider) to assess the severity of someone's UC at diagnosis. After diagnosis, a Mayo score is used to assess severity over time and whether treatment is working

Mechanism of action (MOA)

The process of how a drug works inside the body

Mucosal healing

The absence of blood, erosions, and ulcers in the colon, and the combination of **endoscopic** (nonsurgical procedure used to visually examine a person's digestive tract) and **histological** (the study of tissues and cells under a microscope) findings

Proctocolectomy

A type of surgery that removes the colon and rectum

Small molecule

A drug that can enter cells easily because it has a low molecular weight. Many medications that precisely interact with specific components in your body are small molecules, including RINVOQ

Treatment response

In UC, treatment response is a reduction in UC symptoms and/or an improvement in overall colon appearance, specifically caused by taking medication (as opposed to other factors like diet or exercise)

USE

RINVOQ is a prescription medicine used to treat adults with moderate to severe ulcerative colitis when 1 or more medicines called tumor necrosis factor (TNF) blockers have been used, and did not work well or could not be tolerated. It is not known if RINVOQ is safe and effective in children with ulcerative colitis.

SAFETY CONSIDERATIONS

RINVOQ may cause serious side effects, including:

- **Serious infections.** RINVOQ can lower ability to fight infections. Serious infections, some fatal, occurred, including tuberculosis (TB) and infections caused by bacteria, fungi, or viruses.
- **Increased risk of death in people age 50+ with at least 1 heart disease risk factor.**
- **Cancer and immune system problems.** Increased risk of some cancers, including lymphoma and skin. Current or past smokers have higher risk for lymphoma and lung cancer.
- **Increased risk of major cardiovascular events such as heart attack, stroke, or death in people 50+ with at least 1 heart disease risk factor, especially in current or past smokers.**
- **Blood clots,** some fatal, in veins of the legs or lungs and arteries. This occurred more often in people 50+ with at least 1 heart disease risk factor.
- **Serious allergic reactions. Do not take if allergic to RINVOQ or its ingredients.**
- **Tears in the stomach or intestines; changes in certain laboratory test results.**



Please see additional Important Safety Information on the next page.
Please see the **Full Prescribing Information**, including the **Medication Guide**, for RINVOQ at rxabbvie.com/pdf/rinvoq_pi.pdf and discuss with your doctor.

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IMPORTANT SAFETY INFORMATION

What is the most important information I should know about RINVOQ?

RINVOQ may cause serious side effects, including:

- **Serious infections.** RINVOQ can lower your ability to fight infections. Serious infections have happened while taking RINVOQ, including tuberculosis (TB) and infections caused by bacteria, fungi, or viruses that can spread throughout the body. Some people have died from these infections. Your healthcare provider (HCP) should test you for TB before starting RINVOQ and check you closely for signs and symptoms of TB during treatment with RINVOQ. You should not start taking RINVOQ if you have any kind of infection unless your HCP tells you it is okay. If you get a serious infection, your HCP may stop your treatment until your infection is controlled. You may be at higher risk of developing shingles (herpes zoster).
- **Increased risk of death in people 50 years and older who have at least 1 heart disease (cardiovascular) risk factor.**
- **Cancer and immune system problems.** RINVOQ may increase your risk of certain cancers. Lymphoma and other cancers, including skin cancers, can happen. Current or past smokers are at higher risk of certain cancers, including lymphoma and lung cancer. Follow your HCP's advice about having your skin checked for skin cancer during treatment with RINVOQ. Limit the amount of time you spend in sunlight. Wear protective clothing when you are in the sun and use sunscreen.
- **Increased risk of major cardiovascular (CV) events, such as heart attack, stroke, or death, in people 50 years and older who have at least 1 heart disease (CV) risk factor, especially if you are a current or past smoker.**
- **Blood clots.** Blood clots in the veins of the legs or lungs and arteries can happen with RINVOQ. This may be life-threatening and cause death. Blood clots in the veins of the legs and lungs have happened more often in people who are 50 years and older and with at least 1 heart disease (CV) risk factor.
- **Allergic reactions.** Symptoms such as rash (hives), trouble breathing, feeling faint or dizzy, or swelling of your lips, tongue, or throat, that may mean you are having an allergic reaction have been seen in people taking RINVOQ. Some of these reactions were serious. If any of these symptoms occur during treatment with RINVOQ, stop taking RINVOQ and get emergency medical help right away.

- **Tears in the stomach or intestines.** This happens most often in people who take nonsteroidal anti-inflammatory drugs (NSAIDs) or corticosteroids. Get medical help right away if you get stomach-area pain, fever, chills, nausea, or vomiting.

- **Changes in certain laboratory tests.** Your HCP should do blood tests before you start taking RINVOQ and while you take it. Your HCP may stop your RINVOQ treatment for a period of time if needed because of changes in these blood test results.

Do not take RINVOQ if you are allergic to upadacitinib or any of the ingredients in RINVOQ. See the Medication Guide or Consumer Brief Summary for a complete list of ingredients.

What should I tell my HCP BEFORE starting RINVOQ?

Tell your HCP if you:

- Are being treated for an infection, have an infection that won't go away or keeps coming back, or have symptoms of an infection, such as:
 - Fever, sweating, or chills
 - Muscle aches
 - Cough
 - Shortness of breath
 - Feeling tired
 - Weight loss
 - Warm, red, or painful skin or sores on your body
 - Blood in phlegm
 - Diarrhea or stomach pain
 - Burning when urinating or urinating more often than normal
- Have TB or have been in close contact with someone with TB.
- Are a current or past smoker.
- Have had a heart attack, other heart problems, or stroke.
- Have or have had any type of cancer, hepatitis B or C, shingles (herpes zoster), blood clots in the veins of your legs or lungs, diverticulitis (inflammation in parts of the large intestine), or ulcers in your stomach or intestines.
- Have other medical conditions, including liver problems, low blood cell counts, diabetes, chronic lung disease, HIV, or a weak immune system.
- Live, have lived, or have traveled to parts of the country, such as the Ohio and Mississippi River valleys and the Southwest, that increase your risk of getting certain kinds of fungal infections. If you are unsure if you've been to these types of areas, ask your HCP.
- Have recently received or are scheduled to receive a vaccine. People who take RINVOQ should not receive live vaccines.

Please see additional Important Safety Information on the next page.

Please see the Full Prescribing Information, including the Medication Guide, for RINVOQ at rxabbvie.com/pdf/rinvoq_pi.pdf and discuss with your doctor.

IMPORTANT SAFETY INFORMATION

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- Are pregnant or plan to become pregnant. Based on animal studies, RINVOQ may harm your unborn baby. Your HCP will check whether or not you are pregnant before you start RINVOQ. You should use effective birth control (contraception) to avoid becoming pregnant during treatment with RINVOQ and for 4 weeks after your last dose.
- There is a pregnancy surveillance program for RINVOQ. The purpose of the program is to collect information about the health of you and your baby. If you become pregnant while taking RINVOQ, you are encouraged to report the pregnancy by calling 1-800-633-9110.
- Are breastfeeding or plan to breastfeed. RINVOQ may pass into your breast milk. Do not breastfeed during treatment with RINVOQ and for 6 days after your last dose.

Tell your HCP about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. RINVOQ and other medicines may affect each other, causing side effects.

Especially tell your HCP if you take:

- Medicines for fungal or bacterial infections
- Rifampicin or phenytoin
- Medicines that affect your immune system

If you are not sure if you are taking any of these medicines, ask your HCP or pharmacist.

What should I avoid while taking RINVOQ?

Avoid food or drink containing grapefruit during treatment with RINVOQ as it may increase the risk of side effects.

What should I do or tell my HCP AFTER starting RINVOQ?

- Tell your HCP right away if you have any symptoms of an infection. RINVOQ can make you more likely to get infections or make any infections you have worse.
- Get emergency help right away if you have any symptoms of a heart attack or stroke while taking RINVOQ, including:
 - Discomfort in the center of your chest that lasts for more than a few minutes or that goes away and comes back
 - Severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
 - Pain or discomfort in your arms, back, neck, jaw, or stomach
 - Shortness of breath with or without chest discomfort
 - Breaking out in a cold sweat
 - Nausea or vomiting
 - Feeling lightheaded

- Weakness in one part or on one side of your body
 - Slurred speech
- Tell your HCP right away if you have any signs or symptoms of blood clots during treatment with RINVOQ, including:
 - Swelling
 - Pain or tenderness in one or both legs
 - Sudden unexplained chest or upper back pain
 - Shortness of breath or difficulty breathing
 - Tell your HCP right away if you have a fever or stomach-area pain that does not go away, and a change in your bowel habits.

What are other possible side effects of RINVOQ?

Common side effects include upper respiratory tract infections (common cold, sinus infections), shingles (herpes zoster), herpes simplex virus infections (including cold sores), bronchitis, nausea, cough, fever, acne, headache, increased blood levels of creatine phosphokinase, allergic reactions, inflammation of hair follicles, stomach-area (abdominal) pain, increased weight, flu, tiredness, lower number of certain types of white blood cells (neutropenia, lymphopenia, leukopenia), muscle pain, flu-like illness, rash, increased blood cholesterol levels, increased liver enzyme levels, pneumonia, low number of red blood cells (anemia), and infection of the stomach and intestine (gastroenteritis).

A separation or tear to the lining of the back part of the eye (retinal detachment) has happened in people with atopic dermatitis treated with RINVOQ. Call your HCP right away if you have any sudden changes in your vision during treatment with RINVOQ.

Some people taking RINVOQ may see medicine residue (a whole tablet or tablet pieces) in their stool. If this happens, call your healthcare provider.

These are not all the possible side effects of RINVOQ.

How should I take RINVOQ?

RINVOQ is taken once a day with or without food. Do not split, crush, or chew the tablet. Take RINVOQ exactly as your HCP tells you to use it. RINVOQ is available in 15 mg, 30 mg, and 45 mg extended-release tablets.

This is the most important information to know about RINVOQ. For more information, talk to your HCP.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

If you are having difficulty paying for your medicine, AbbVie may be able to help. Visit AbbVie.com/myAbbVieAssist to learn more.

Please see the [Full Prescribing Information](#), including the [Medication Guide](#), for RINVOQ at rxabbvie.com/pdf/rinvoq_pi.pdf and discuss with your doctor.