

# DISCUSSION GUIDE



# A guide to help navigate conversations with your gastroenterologist

Ulcerative colitis (UC) flare-ups are hard, and sometimes getting through them may be the only thing you can focus on. But it's important to be proactive and think about lasting remission as well.

Use this guide at your appointment to explain the impact of UC on your daily life so you and your doctor can work together to find a treatment that's right for you.

# To help guide the conversation, select your responses:



How often do you experience flare-ups (periods of time when you're experiencing symptoms)?

A few times	Every te
a year	months
Monthly	Several t

Constantly

Several times a month

See questions on next page

# **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 pages 4 and 5. Please see the **Full Prescribing Information**, including the **Medication Guide**, for RINVOQ at **rxabbvie.com/pdf/rinvoq\_pi.pdf** and discuss with your doctor.

2	When you're experiencing UC symptoms, how many times a day do you go to the bathroom?	1-3 4-6	7-8 9 or more			
	When you go to the bathroom, how often do you have blood in your stool?	Never Some of the time	Most of the time Every time			
3	When you feel the urgent need to go to the bathroom, do you have an actual bowel movement?	Yes	No Sometimes			
	Your gastroenterologist may use the term " Tell your doctor how often you feel the need	= -				
4	Overall, how does UC impact your life? (Select all that apply.)	I can't enjoy n	nyself when I am out, in fear of cident			
E. C.	I miss work or school	I need to be prepared for accidents every time I leave the house  I avoid going out to dinner with others				
	I feel like I'm not available for my family/friends					
	I cancel plans in fear of having an accident	I feel too tired and concentr	l to run errands, see others, rate at work			
		Other:				
5	Are you familiar with how inflammation contributes to your UC symptoms?	Yes	No Somewhat			
	Inflammation is your immune system's defense against things that are trying to make you sick. But with					

Inflammation is your immune system's defense against things that are trying to make you sick. But with UC, your immune system becomes overactive and attacks the colon, which can lead to a cycle of more inflammation, symptoms, and colon damage.

See questions on next page

# **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 pages 4 and 5. Please see the **Full Prescribing Information**, including the **Medication Guide**, for RINVOQ at **rxabbvie.com/pdf/rinvoq\_pi.pdf** and discuss with your doctor.

6	Have you and your gastroenterologist disoptions that proactively treat your UC raijust addressing the symptoms?		Yes No	l'd like to have more conversations with my doctor	
7	Your gastroenterologist may talk about "repairing the colon lining." Are you familiar with this term?	Yes	No	Not completely	
	In this case, repairing the colon lining means that evidence of active UC cannot be seen during an endoscopy or with any other way of looking at the lining of the colon.				
8	Are you currently in steroid-free remission?	Yes	No No	Not sure	
	If "no" or "not sure" and you are currently on a treatment, are you experiencing any of the following symptoms? (Select all that apply.)	Fatigue Sudden accidents Abdominal pain	More frequent bathroom trips Urgency to find a bathroom	Bloody stools  None of the above	
	Talk with your gastroenterologist about what lasting, steroid-free remission looks like and would mean for you.				
9	Are you ready to talk with your gastroent about a treatment option that goes beyon symptom relief to treat the inflammation lead to your UC symptoms?	nd	Yes	l'd like to learn more about this option first	
	Being proactive about your treatment can he steroid-free remission and give the colon linir			achieve lasting,	
			your life. Ask yo		

# **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 pages 4 and 5. Please see the **Full Prescribing Information**, including the **Medication Guide**, for RINVOQ at **rxabbvie.com/pdf/rinvoq\_pi.pdf** and discuss with your doctor.

# **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.

# 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 lifethreatening 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
  - Shortness of breath
  - Warm, red, or painful skin or sores on your body
- Muscle aches
- Feeling tired
- Blood in phlegm
- Diarrhea or stomach pain
- Cough
- Weight loss
- 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 (continued from previous page)

- 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 stomacharea 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.