RINVOQ®
upadacitinib
ONE PILL, ONCE-DAILY

For moderate to severe atopic dermatitis (AD) patients 12+ years not adequately controlled with other systemic drugs, including biologics.[1]

GETTING PATIENTS STARTED

BEGINNING TREATMENT AND LAB MONITORING WITH RINVOQ

"RINVOQ works for me."
MICHAEL S., RINVOQ patient

INDICATION[1]

RINVOQ is indicated for the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable.

Limitations of Use: RINVOQ is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

IMPORTANT SAFETY INFORMATION[1]

SERIOUS INFECTIONS

Patients treated with RINVOQ are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants, such as methotrexate or corticosteroids. If a serious infection develops, interrupt RINVOQ until the infection is controlled.

Reported infections include:

- **Active tuberculosis (TB), which may present with pulmonary or extrapulmonary disease. Test patients for latent TB before RINVOQ use and during therapy. Consider treatment for latent TB infection prior to RINVOQ use.**
- **Invasive fungal infections, including cryptococcosis and pneumocystosis.**
- **Bacterial, viral, including herpes zoster, and other infections due to opportunistic pathogens.**

Carefully consider the risks and benefits of treatment with RINVOQ prior to initiating therapy in patients with chronic or recurrent infection. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with RINVOQ, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

Please see additional Important Safety Information, including BOXED WARNING on Serious Infections, Mortality, Malignancies, Major Adverse Cardiovascular Events, and Thrombosis, throughout and on pages 10-11.

Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/rinvoq_pi.pdf

1 PATIENT SELECTION

PRESCRIBING DECISIONS SHOULD ALWAYS WEIGH BENEFIT/RISK[1]

- **AGE 12+**
- **REFRACTORY, MODERATE TO SEVERE AD** (atopic dermatitis)
- **NOT ADEQUATELY CONTROLLED WITH OTHER SYSTEMIC DRUGS, INCLUDING BIOLOGICS, OR WHEN USE OF THOSE THERAPIES IS INADVISABLE**

RINVOQ is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.[1]

"RINVOQ is now a part of my daily routine."
LOGAN, RINVOQ patient

IMPORTANT SAFETY INFORMATION[1] (cont'd)

MORTALITY

In a large, randomized, postmarketing safety study comparing another Janus kinase (JAK) inhibitor with tumor necrosis factor (TNF) blockers in rheumatoid arthritis (RA) patients ≥50 years old with at least one cardiovascular (CV) risk factor, a higher rate of all-cause mortality, including sudden CV death, was observed with the JAK inhibitor. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with RINVOQ.

MALIGNANCIES

Lymphoma and other malignancies have been observed in patients treated with RINVOQ.

In a large, randomized, postmarketing safety study comparing another JAK inhibitor with TNF blockers in RA patients, a higher rate of malignancies (excluding non-melanoma skin cancer [NMSC]), lymphomas, and lung cancer (in current or past smokers) was observed with the JAK inhibitor. Patients who are current or past smokers are at additional increased risk.

With RINVOQ, consider the benefits and risks for the individual patient prior to initiating or continuing therapy, particularly in patients with a known malignancy (other than a successfully treated NMSC), patients who develop a malignancy when on treatment, and patients who are current or past smokers. NMSCs have been reported in patients treated with RINVOQ. Periodic skin examination is recommended for patients who are at increased risk for skin cancer. Advise patients to limit sunlight exposure by wearing protective clothing and using sunscreen.

For moderate to severe atopic dermatitis (AD) patients 12+ years not adequately controlled with other systemic drugs, including biologics.[1]

RINVOQ® upadacitinib
ONE PILL, ONCE-DAILY

2 BASELINE SCREENING

AT BASELINE AND PERIODICALLY, SCREEN FOR:

SERIOUS INFECTIONS[1]

Closely monitor patients for the development of signs and symptoms of infection during and after treatment with RINVOQ. Interrupt RINVOQ if a patient develops a serious or opportunistic infection.

TUBERCULOSIS[1]

Monitor patients for the development of signs and symptoms of TB, including patients who tested negative for latent TB infection prior to initiating therapy.

VIRAL REACTIVATION[1]

Screening for viral hepatitis and monitoring for reactivation should be performed in accordance with clinical guidelines before starting and during therapy with RINVOQ.

PREGNANCY[1]

Based on animal studies, RINVOQ may cause embryo-fetal toxicity when administered to pregnant women. Verify pregnancy status prior to starting treatment. Advise women to use effective contraception during and for 4 weeks after completion of treatment.

VACCINATIONS[1]

Avoid use of live vaccines during, or immediately prior to, RINVOQ therapy. Prior to initiating RINVOQ, patients should be brought up to date on all immunizations, including prophylactic varicella zoster or herpes zoster vaccinations, in agreement with current immunization guidelines.

IMPORTANT SAFETY INFORMATION[1] (cont'd)

MAJOR ADVERSE CARDIOVASCULAR EVENTS

In a large, randomized, postmarketing study comparing another JAK inhibitor with TNF blockers in RA patients ≥50 years old with at least one CV risk factor, a higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction, and stroke) was observed with the JAK inhibitor. Patients who are current or past smokers are at additional increased risk. Discontinue RINVOQ in patients that have experienced a myocardial infarction or stroke.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with RINVOQ, particularly in patients who are current or past smokers and patients with other CV risk factors. Patients should be informed about the symptoms of serious CV events and the steps to take if they occur.

Please see additional Important Safety Information, including BOXED WARNING on Serious Infections, Mortality, Malignancies, Major Adverse Cardiovascular Events, and Thrombosis, throughout and on pages 10-11.

Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/rinvoq_pi.pdf

3 LAB MONITORING

PERFORM LAB TESTS AT BASELINE,* AT 12 WEEKS,† AND PERIODICALLY THEREAFTER[1,2]

	LABORATORY VALUE	Treatment should NOT be INITIATED or CONTINUED if
CBC Differential	**Neutrophils**	<1,000 cells/mm^3
	Lymphocytes	<500 cells/mm^3
	Hemoglobin	<8 g/dL
	Liver enzymes	Elevated liver enzymes and suspected drug-induced injury
	Lipids	–

*USPI recommendation for CBC and liver enzymes: at baseline and periodically thereafter.
†USPI recommendation for lipids: at 12 weeks and thereafter according to hyperlipidemia guidelines.

Treatment may be restarted when blood levels return to acceptable values as seen in chart above, drug-induced liver diagnosis is excluded, or infection is controlled.[1]

Discontinue RINVOQ in patients that have experienced a myocardial infarction or stroke.[1]

Avoid RINVOQ in patients that may be at increased risk of thrombosis.[1]

IMPORTANT SAFETY INFORMATION[1] (cont'd)

THROMBOSIS

Thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis have occurred in patients treated with JAK inhibitors used to treat inflammatory conditions. Many of these adverse events were serious and some resulted in death.

In a large, randomized, postmarketing study comparing another JAK inhibitor to TNF blockers in RA patients ≥50 years old with at least one CV risk factor, a higher rate of thrombosis was observed with the JAK inhibitor. Avoid RINVOQ in patients at risk. Patients with symptoms of thrombosis should discontinue RINVOQ and be promptly evaluated.

HYPERSENSITIVITY

RINVOQ is **contraindicated** in patients with known hypersensitivity to upadacitinib or any of its excipients. Serious hypersensitivity reactions, such as anaphylaxis and angioedema, were reported in patients receiving RINVOQ in clinical trials. If a clinically significant hypersensitivity reaction occurs, discontinue RINVOQ and institute appropriate therapy.

GASTROINTESTINAL PERFORATIONS

Gastrointestinal (GI) perforations have been reported in clinical trials with RINVOQ. Monitor RINVOQ-treated patients who may be at risk for gastrointestinal perforation (e.g., patients with a history of diverticulitis and patients taking NSAIDs or corticosteroids). Promptly evaluate patients presenting with new onset abdominal pain for early identification of GI perforation.

For moderate to severe atopic dermatitis (AD) patients 12+ years not adequately controlled with other systemic drugs, including biologics.[1]

RINVOQ® upadacitinib
ONE PILL, ONCE-DAILY

LAB ABNORMALITIES

PLACEBO-CONTROLLED PERIOD THROUGH 16 WEEKS[1,3,4]

~99% OF PATIENTS DID NOT EXPERIENCE A TREATMENT INTERRUPTION DUE TO LAB CHANGES.[3]

		All Subjects‡		
	Lab Abnormality	**Placebo** (n=902)	**RINVOQ 15 mg** (n=899)	**RINVOQ 30 mg** (n=906)
Absolute neutrophil count	<1,000 cells/µL	**0%**	**0.4%**	**1.3%**
Absolute lymphocyte count	<500 cells/µL	**0.1%**	**0.1%**	**0.3%**
Hemoglobin	<8 g/dL	**0%**	**0%**	**0.1%**
Liver transaminases	ALT ≥3 ULN	**1.1%**	**0.7%**	**1.4%**
	AST ≥3 ULN	**0.9%**	**1.2%**	**1.1%**
Lipids	LDL-C elevation (mean change from baseline)	**1.68 mg/dL**	**8.09 mg/dL**	**13.35 mg/dL**
	HDL-C elevation (mean change from baseline)	**1.22 mg/dL**	**7.11 mg/dL**	**9.35 mg/dL**

‡Includes subjects from M16-048, MEASURE UP 1, MEASURE UP 2, and AD UP.
ALT=alanine aminotransferase; AST=aspartate transaminase; HDL=high-density lipoprotein cholesterol; LDL= low-density lipoprotein cholesterol; ULN=upper limit of normal.

Lab changes (ANC, ALC, Hgb, LFT) occurred within the first 4-8 weeks, were transient, and generally returned to baseline levels within the normal range without study drug discontinuation.[3-5]

IMPORTANT SAFETY INFORMATION[1] (cont'd)

LABORATORY ABNORMALITIES

Neutropenia

Treatment with RINVOQ was associated with an increased incidence of neutropenia (absolute neutrophil count [ANC] <1000 cells/mm^3). Treatment with RINVOQ is not recommended in patients with an ANC <1000 cells/mm^3. Evaluate neutrophil counts at baseline and thereafter according to routine patient management.

Please see additional Important Safety Information, including BOXED WARNING on Serious Infections, Mortality, Malignancies, Major Adverse Cardiovascular Events, and Thrombosis, throughout and on pages 10-11.

Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/rinvoq_pi.pdf

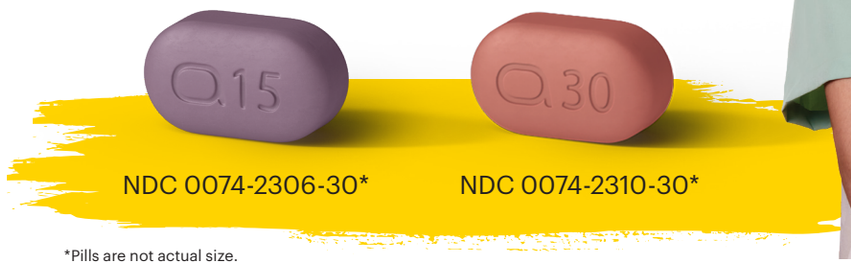
ONE PILL, ONCE-DAILY[1]

AN ORAL JAK INHIBITOR FOR THE TREATMENT OF REFRACTORY, MODERATE TO SEVERE AD[1]

"One pill once a day, that's **one of the things I like** about RINVOQ."

JOSH, **RINVOQ patient**

Increasing to 30 mg from 15 mg, due to inadequate response, is possible with RINVOQ for appropriate patients.



*Pills are not actual size.

IMPORTANT SAFETY INFORMATION[1] (cont'd)

Lymphopenia

Absolute lymphocyte counts (ALC) <500 cells/mm^3 were reported in RINVOQ-treated patients. Treatment with RINVOQ is not recommended in patients with an ALC <500 cells/mm^3. Evaluate at baseline and thereafter according to routine patient management.

Anemia

Decreases in hemoglobin levels to <8 g/dL were reported in RINVOQ-treated patients. Treatment should not be initiated or should be interrupted in patients with hemoglobin levels <8 g/dL. Evaluate at baseline and thereafter according to routine patient management.

Lipids

Treatment with RINVOQ was associated with increases in lipid parameters, including total cholesterol, low-density lipoprotein (LDL) cholesterol, and high-density lipoprotein (HDL) cholesterol. Manage patients according to clinical guidelines for the management of hyperlipidemia. Evaluate patients 12 weeks after initiation of treatment and thereafter according to the clinical guidelines for hyperlipidemia.

Liver enzyme elevations

Treatment with RINVOQ was associated with increased incidence of liver enzyme elevation compared to placebo.

For moderate to severe atopic dermatitis (AD) patients 12+ years not adequately controlled with other systemic drugs, including biologics.[1]

RINVOQ® upadacitinib

ONE PILL, ONCE-DAILY

INITIATION[1]

For patients 12+ weighing at least 88 lb (40 kg), initiate therapy with 15 mg once-daily.

For patients **≥65** years of age, patients receiving strong **CYP3A4 inhibitors,** and patients with severe **renal impairment** (eGFR 15 to <30 mL/min/1.73 m^2), the **recommended dose** of RINVOQ is **15 mg** once-daily.

RINVOQ is not recommended for use in: Patients with end stage renal disease (eGFR <15 mL/min/1.73 m^2), severe hepatic impairment (Child-Pugh C), or those receiving strong CYP3A4 inducers.

TREATMENT[1]

For patients 12 to <65 years of age weighing at least 88 lb (40 kg):

- If an adequate response is not achieved, consider increasing dosage to 30 mg once-daily
- Discontinue RINVOQ if an adequate response is not achieved with the 30 mg dose
- Use the lowest effective dose needed to maintain response

ADMINISTRATION[1]

- Take 1 tablet once-daily with or without food
- Advise patients to avoid food or drink containing grapefruit during treatment with RINVOQ
- RINVOQ is an extended-release tablet. Do not split, crush, or chew. Ensure tablet is swallowed whole

IMPORTANT SAFETY INFORMATION[1] (cont'd)

Liver enzyme elevations (cont'd)

Evaluate at baseline and thereafter according to routine patient management. Prompt investigation of the cause of liver enzyme elevation is recommended to identify potential cases of drug-induced liver injury. If increases in aspartate aminotransferase (AST) or alanine aminotransferase (ALT) are observed during routine patient management and drug-induced liver injury is suspected, RINVOQ should be interrupted until this diagnosis is excluded.

EMBRYO-FETAL TOXICITY

Based on findings in animal studies, RINVOQ may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with RINVOQ and for 4 weeks after the final dose. Verify pregnancy status of females of reproductive potential prior to starting treatment with RINVOQ.

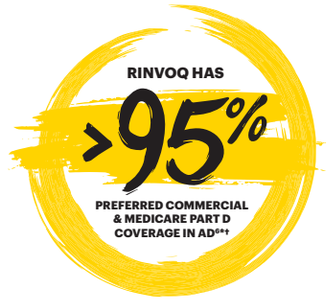
Please see additional Important Safety Information, including BOXED WARNING on Serious Infections, Mortality, Malignancies, Major Adverse Cardiovascular Events, and Thrombosis, throughout and on pages 10-11.

Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/rinvoq_pi.pdf

PATIENT SUPPORT

RINVOQ Complete can provide your patients support to help them start and stay on track with their prescribed treatment.

Complete and send the enrollment and prescription form to the patient's specialty pharmacy and to RINVOQ Complete. Once enrolled, patients can get help with:



National Commercial and Medicare Part D Formulary coverage under the pharmacy benefit as of January 2024.[6]

$5

Affordability:
Eligible, commercially insured patients may pay as little as $5 per month on their prescription and can be reimbursed for out-of-pocket costs related to lab tests and monitoring‡

1-to-1 support from Insurance Specialists and Nurse Ambassadors§

RINVOQ Complete Bridging Resource: No-cost option for eligible, commercially insured RINVOQ patients enables earliest treatment start‖

ENROLL YOUR PATIENTS IN RINVOQ® COMPLETE
RINVOQHCP.COM/AD/COMPLETE

IMPORTANT SAFETY INFORMATION[1] (cont'd)

VACCINATION
Avoid use of live vaccines during, or immediately prior to, RINVOQ therapy. Prior to initiating RINVOQ, patients should be brought up to date on all immunizations, including prophylactic varicella zoster or herpes zoster vaccinations, in agreement with current immunization guidelines.

MEDICATION RESIDUE IN STOOL
Reports of medication residue in stool or ostomy output have occurred in patients taking RINVOQ. Most reports described anatomic or functional GI conditions with shortened GI transit times. Instruct patients to contact their healthcare provider if medication residue is observed repeatedly. Monitor patients clinically and consider alternative treatment if there is an inadequate therapeutic response.

LACTATION
There are no data on the presence of RINVOQ in human milk, the effects on the breastfed infant, or the effects on milk production. Available data in animals have shown the excretion of RINVOQ in milk. Advise patients that breastfeeding is not recommended during treatment with RINVOQ and for 6 days after the last dose.

For moderate to severe atopic dermatitis (AD) patients 12+ years not adequately controlled with other systemic drugs, including biologics.[1]

RINVOQ® upadacitinib
ONE PILL, ONCE-DAILY

EDUCATE YOUR PATIENTS ABOUT LAB TESTING REIMBURSEMENT HELP THROUGH RINVOQ® COMPLETE

*RINVOQ is on a preferred tier or otherwise has preferred status on the plan's formulary.

†Coverage requirements and benefit designs vary by payer and may change over time. Please consult with payers directly for the most current reimbursement policies.

‡Eligibility: Available to patients with commercial insurance coverage for RINVOQ® (upadacitinib) who meet eligibility criteria. This co-pay assistance program is not available to patients receiving prescription reimbursement under any federal, state, or government-funded insurance programs (for example, Medicare [including Part D], Medicare Advantage, Medigap, Medicaid, TRICARE, Department of Defense, or Veterans Affairs programs) or where prohibited by law. Offer subject to change or termination without notice. Restrictions, including monthly maximums, may apply. This is not health insurance. **For full Terms and Conditions, visit RINVOQSavingsCard.com or call 1.800.2RINVOQ for additional information.** To learn about AbbVie's privacy practices and your privacy choices, visit https://privacy.abbvie.

§Nurse Ambassadors are provided by AbbVie and do not provide medical advice or work under the direction of the prescribing health care professional (HCP). They are trained to direct patients to speak with their HCP about any treatment-related questions, including further referrals.

‖Eligibility criteria: Available to patients aged 63 or younger with commercial insurance coverage. Patients must have a valid prescription for RINVOQ for an FDA approved indication and a denial of insurance coverage based on a prior authorization request on file along with a confirmation of appeal. Continued eligibility for the program requires the submission of an appeal of the coverage denial every 180 days. Program provides for RINVOQ at no charge to patients for up to two years or until they receive insurance coverage approval, whichever occurs earlier, and is not contingent on purchase requirements of any kind. Program is not available to patients whose medications are reimbursed in whole or in part by Medicare, Medicaid, TRICARE, or any other federal or state program. Offer subject to change or discontinuance without notice. This is not health insurance and program does not guarantee insurance coverage. No claims for payment may be submitted to any third party for product dispensed by program. Limitations may apply.

IMPORTANT SAFETY INFORMATION[1] (cont'd)

HEPATIC IMPAIRMENT
RINVOQ is not recommended for use in patients with severe hepatic impairment.

ADVERSE REACTIONS
The most common adverse reactions in RINVOQ clinical trials were upper respiratory tract infections, herpes zoster, herpes simplex, bronchitis, nausea, cough, pyrexia, acne, headache, increased blood creatine phosphokinase, hypersensitivity, folliculitis, abdominal pain, increased weight, influenza, fatigue, neutropenia, myalgia, influenza-like illness, elevated liver enzymes, rash, and anemia.

Inform patients that retinal detachment has been reported in clinical trials with RINVOQ. Advise patients to immediately inform their healthcare provider if they develop any sudden changes in vision while receiving RINVOQ.

Dosage Forms and Strengths: RINVOQ is available in 15 mg, 30 mg, and 45 mg extended-release tablets.

Please see additional Important Safety Information, including BOXED WARNING on Serious Infections, Mortality, Malignancies, Major Adverse Cardiovascular Events, and Thrombosis, throughout and on pages 10-11.

Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/rinvoq_pi.pdf

INDICATION[1]

RINVOQ is indicated for the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable.

Limitations of Use: RINVOQ is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

IMPORTANT SAFETY INFORMATION[1]

SERIOUS INFECTIONS

Patients treated with RINVOQ are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants, such as methotrexate or corticosteroids. If a serious infection develops, interrupt RINVOQ until the infection is controlled.

Reported infections include:

- **Active tuberculosis (TB), which may present with pulmonary or extrapulmonary disease. Test patients for latent TB before RINVOQ use and during therapy. Consider treatment for latent TB infection prior to RINVOQ use.**
- **Invasive fungal infections, including cryptococcosis and pneumocystosis.**
- **Bacterial, viral, including herpes zoster, and other infections due to opportunistic pathogens.**

Carefully consider the risks and benefits of treatment with RINVOQ prior to initiating therapy in patients with chronic or recurrent infection. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with RINVOQ, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

MORTALITY

In a large, randomized, postmarketing safety study comparing another Janus kinase (JAK) inhibitor with tumor necrosis factor (TNF) blockers in rheumatoid arthritis (RA) patients ≥50 years old with at least one cardiovascular (CV) risk factor, a higher rate of all-cause mortality, including sudden CV death, was observed with the JAK inhibitor. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with RINVOQ.

MALIGNANCIES

Lymphoma and other malignancies have been observed in patients treated with RINVOQ.

In a large, randomized, postmarketing safety study comparing another JAK inhibitor with TNF blockers in RA patients, a higher rate of malignancies (excluding non-melanoma skin cancer [NMSC]), lymphomas, and lung cancer (in current or past smokers) was observed with the JAK inhibitor. Patients who are current or past smokers are at additional increased risk.

With RINVOQ, consider the benefits and risks for the individual patient prior to initiating or continuing therapy, particularly in patients with a known malignancy (other than a successfully treated NMSC), patients who develop a malignancy when on treatment, and patients who are current or past smokers. NMSCs have been reported in patients treated with RINVOQ. Periodic skin examination is recommended for patients who are at increased risk for skin cancer. Advise patients to limit sunlight exposure by wearing protective clothing and using sunscreen.

MAJOR ADVERSE CARDIOVASCULAR EVENTS

In a large, randomized, postmarketing study comparing another JAK inhibitor with TNF blockers in RA patients ≥50 years old with at least one CV risk factor, a higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction, and stroke) was observed with the JAK inhibitor. Patients who are current or past smokers are at additional increased risk. Discontinue RINVOQ in patients that have experienced a myocardial infarction or stroke.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with RINVOQ, particularly in patients who are current or past smokers and patients with other CV risk factors. Patients should be informed about the symptoms of serious CV events and the steps to take if they occur.

THROMBOSIS

Thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis have occurred in patients treated with JAK inhibitors used to treat inflammatory conditions. Many of these adverse events were serious and some resulted in death.

In a large, randomized, postmarketing study comparing another JAK inhibitor to TNF blockers in RA patients ≥50 years old with at least one CV risk factor, a higher rate of thrombosis was observed with the JAK inhibitor. Avoid RINVOQ in patients at risk. Patients with symptoms of thrombosis should discontinue RINVOQ and be promptly evaluated.

HYPERSENSITIVITY

RINVOQ is **contraindicated** in patients with known hypersensitivity to upadacitinib or any of its excipients. Serious hypersensitivity reactions, such as anaphylaxis and angioedema, were reported in patients receiving RINVOQ in clinical trials. If a clinically significant hypersensitivity reaction occurs, discontinue RINVOQ and institute appropriate therapy.

GASTROINTESTINAL PERFORATIONS

Gastrointestinal (GI) perforations have been reported in clinical trials with RINVOQ. Monitor RINVOQ-treated patients who may be at risk for gastrointestinal perforation (e.g., patients with a history of diverticulitis and patients taking NSAIDs or corticosteroids). Promptly evaluate patients presenting with new onset abdominal pain for early identification of GI perforation.

LABORATORY ABNORMALITIES

Neutropenia

Treatment with RINVOQ was associated with an increased incidence of neutropenia (absolute neutrophil count [ANC] <1000 cells/mm^3). Treatment with RINVOQ is not recommended in patients with an ANC <1000 cells/mm^3. Evaluate neutrophil counts at baseline and thereafter according to routine patient management.

Lymphopenia

Absolute lymphocyte counts (ALC) <500 cells/mm^3 were reported in RINVOQ-treated patients. Treatment with RINVOQ is not recommended in patients with an ALC <500 cells/mm^3. Evaluate at baseline and thereafter according to routine patient management.

Anemia

Decreases in hemoglobin levels to <8 g/dL were reported in RINVOQ-treated patients. Treatment should not be initiated or should be interrupted in patients with hemoglobin levels <8 g/dL. Evaluate at baseline and thereafter according to routine patient management.

Lipids

Treatment with RINVOQ was associated with increases in lipid parameters, including total cholesterol, low-density lipoprotein (LDL) cholesterol, and high-density lipoprotein (HDL) cholesterol. Manage patients according to clinical guidelines for the management of hyperlipidemia. Evaluate patients 12 weeks after initiation of treatment and thereafter according to the clinical guidelines for hyperlipidemia.

Liver enzyme elevations

Treatment with RINVOQ was associated with increased incidence of liver enzyme elevation compared to placebo. Evaluate at baseline and thereafter according to routine patient management. Prompt investigation of the cause of liver enzyme elevation is recommended to identify potential cases of drug-induced liver injury. If increases in aspartate aminotransferase (AST) or alanine aminotransferase (ALT) are observed during routine patient management and drug-induced liver injury is suspected, RINVOQ should be interrupted until this diagnosis is excluded.

EMBRYO-FETAL TOXICITY

Based on findings in animal studies, RINVOQ may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with RINVOQ and for 4 weeks after the final dose. Verify pregnancy status of females of reproductive potential prior to starting treatment with RINVOQ.

VACCINATION

Avoid use of live vaccines during, or immediately prior to, RINVOQ therapy. Prior to initiating RINVOQ, patients should be brought up to date on all immunizations, including prophylactic varicella zoster or herpes zoster vaccinations, in agreement with current immunization guidelines.

MEDICATION RESIDUE IN STOOL

Reports of medication residue in stool or ostomy output have occurred in patients taking RINVOQ. Most reports described anatomic or functional GI conditions with shortened GI transit times. Instruct patients to contact their healthcare provider if medication residue is observed repeatedly. Monitor patients clinically and consider alternative treatment if there is an inadequate therapeutic response.

RINVOQ® upadacitinib

ONE PILL, ONCE-DAILY

LACTATION

There are no data on the presence of RINVOQ in human milk, the effects on the breastfed infant, or the effects on milk production. Available data in animals have shown the excretion of RINVOQ in milk. Advise patients that breastfeeding is not recommended during treatment with RINVOQ and for 6 days after the last dose.

HEPATIC IMPAIRMENT

RINVOQ is not recommended for use in patients with severe hepatic impairment.

ADVERSE REACTIONS

The most common adverse reactions in RINVOQ clinical trials were upper respiratory tract infections, herpes zoster, herpes simplex, bronchitis, nausea, cough, pyrexia, acne, headache, increased blood creatine phosphokinase, hypersensitivity, folliculitis, abdominal pain, increased weight, influenza, fatigue, neutropenia, myalgia, influenza-like illness, elevated liver enzymes, rash, and anemia.

Inform patients that retinal detachment has been reported in clinical trials with RINVOQ. Advise patients to immediately inform their healthcare provider if they develop any sudden changes in vision while receiving RINVOQ.

Dosage Forms and Strengths: RINVOQ is available in 15 mg, 30 mg, and 45 mg extended-release tablets.

Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/rinvoq_pi.pdf

References: 1. RINVOQ [package insert]. North Chicago, IL: AbbVie Inc.; 2023. **2.** Nash P, Kerschbaumer A, Dörner T, et al. Points to consider for the treatment of immune-mediated inflammatory diseases with Janus kinase inhibitors: a consensus statement. *Ann Rheum Dis*. 2021;80(1):71-87. **3.** Data on File. ABVRRTI71891. **4.** Data on File. ABVRRTI71865. **5.** Guttman-Yassky E, Teixeira HD, Simpson EL, et al. Once-daily upadacitinib versus placebo in adolescents and adults with moderate-to-severe atopic dermatitis (Measure Up 1 and Measure Up 2): results from two replicate double-blind, randomized controlled phase 3 trials. *Lancet*. 2021;397(10290):2151-2168. **6.** Data on File, AbbVie Inc. January 2024.

Please see additional Important Safety Information, including BOXED WARNING on Serious Infections, Mortality, Malignancies, Major Adverse Cardiovascular Events, and Thrombosis, throughout and on pages 10 and 11.

Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/rinvoq_pi.pdf

abbvie