SEE INSIDE 1-YEAR EFFICACY AND SAFETY DATA

RINVOQ® upadacitinib

For active ankylosing spondylitis (AS) in adult TNFi-IR patients[1]

For active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation in adult TNFi-IR patients[1]

RAPID & DURABLE DISEASE CONTROL IN AS & NR-AXSPA[1-3]

RINVOQ met its **ASAS40 primary endpoint at Week 14** in 2 clinical studies, with responses observed at Week 4 (AS), Week 2 (nr-axSpA), and up to 1 year.[1-5]

Scan this code to learn more about RINVOQ or visit RINVOQhcp.com/axspa

INDICATIONS[1]

RINVOQ is indicated for the treatment of:

- **Moderately to severely active rheumatoid arthritis (RA)** in adults who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.
- **Active psoriatic arthritis (PsA)** in adults who have had an inadequate response or intolerance to one or more TNF blockers.
- **Active ankylosing spondylitis (AS)** in adults who have had an inadequate response or intolerance to one or more TNF blockers.
- **Active non-radiographic axial spondyloarthritis (nr-axSpA)** with objective signs of inflammation in adults who have had an inadequate response or intolerance to TNF blocker therapy.

Limitations of Use: RINVOQ is not recommended for use in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (bDMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine.

SAFETY CONSIDERATIONS[1]

Serious Infections: RINVOQ-treated patients are at increased risk of serious bacterial (including tuberculosis [TB]), fungal, viral, and opportunistic infections leading to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants, such as methotrexate or corticosteroids.

Mortality: A higher rate of all-cause mortality, including sudden cardiovascular (CV) death, was observed with a Janus kinase inhibitor (JAKi) in a study comparing another JAKi with tumor necrosis factor (TNF) blockers in rheumatoid arthritis (RA) patients ≥50 years with ≥1 CV risk factor.

Malignancies: Malignancies have occurred in RINVOQ-treated patients. A higher rate of lymphomas and lung cancer (in current or past smokers) was observed with another JAKi when compared with TNF blockers in RA patients.

Major Adverse Cardiovascular Events: A higher rate of CV death, myocardial infarction, and stroke was observed with a JAKi in a study comparing another JAKi with TNF blockers in RA patients ≥50 years with ≥1 CV risk factor. History of smoking increases risk.

Thrombosis: Deep venous thrombosis, pulmonary embolism, and arterial thrombosis have occurred in patients treated with JAK inhibitors used to treat inflammatory conditions. A higher rate of thrombosis was observed with another JAKi when compared with TNF blockers in RA patients.

Hypersensitivity: RINVOQ is contraindicated in patients with hypersensitivity to RINVOQ or its excipients.

Other Serious Adverse Reactions: Hypersensitivity Reactions, Gastrointestinal Perforations, Laboratory Abnormalities, and Embryo-Fetal Toxicity.

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

ASAS=Assessment of SpondyloArthritis international Society; IR=intolerance or inadequate response; TNFi=tumor necrosis factor inhibitor.

ONE PILL ONCE A DAY[1,3]

RINVOQ® upadacitinib

The recommended dosage of RINVOQ in AS and nr-axSpA is **15 mg** once daily.

Limitations of Use: RINVOQ is not recommended for use in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (bDMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine.

- Take one pill 1 time a day with or without food
- Advise patients to avoid food or drink containing grapefruit during treatment with RINVOQ
- Instruct patients to notify their healthcare provider if they repeatedly notice intact RINVOQ tablet or fragments in stool or ostomy output
- Store at 36°F to 77°F (2°C to 25°C) in the original bottle in order to protect from moisture
- Swallow pill whole. Do not split, crush, or chew
- The mean terminal elimination half-life of RINVOQ ranged from 8 to 14 hours

Not actual size.

Arthritis Foundation Ease of Use®

SAFETY CONSIDERATIONS[1]

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Mortality: A higher rate of all-cause mortality, including sudden cardiovascular (CV) death, was observed with a Janus kinase inhibitor (JAKi) in a study comparing another JAKi with tumor necrosis factor (TNF) blockers in rheumatoid arthritis (RA) patients ≥50 years with ≥1 CV risk factor.

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- **Active psoriatic arthritis (PsA)** in adults who have had an inadequate response or intolerance to one or more TNF blockers.
- **Active ankylosing spondylitis (AS)** in adults who have had an inadequate response or intolerance to one or more TNF blockers.
- **Active non-radiographic axial spondyloarthritis (nr-axSpA)** with objective signs of inflammation in adults who have had an inadequate response or intolerance to TNF blocker therapy.

Limitations of Use: RINVOQ is not recommended for use in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (bDMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine.

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RAPID & DURABLE DISEASE CONTROL IN *AS* & *NR-AXSPA*[1-5]

Durable Response Rates Out to 1 Year[1-5]

SELECT-AXIS 2: NRI-MI data

ASAS40

Study 1: AS (bDMARD-IR)

Week 14 (primary endpoint):
44.5% RINVOQ (n=211) vs 18.2% placebo (n=209)*

- **Week 4: 22%** RINVOQ vs 12% placebo†
- **Week 52: 65.9%** RINVOQ

Study 2: nr-axSpA (mixed‡)

Week 14 (primary endpoint):
44.9% RINVOQ (n=156) vs 22.3% placebo (n=157)*

- **Week 2: 12%** RINVOQ vs 6% placebo†
- **Week 52: 62.8%** RINVOQ vs 42.7% placebo

RINVOQ is indicated for TNFi-IR patients.

ASDAS-CRP Low Disease Activity

Study 1: AS (bDMARD-IR)

Week 14 (ranked secondary endpoint):
44% RINVOQ (n=211) vs 10% placebo (n=209)*

- **Week 52: 57%** RINVOQ

Study 2: nr-axSpA (mixed‡)

Week 14 (ranked secondary endpoint):
42% RINVOQ (n=156) vs 18% placebo (n=157)*

- **Week 52: 56%** RINVOQ vs 33% placebo

*$P<0.0001$.[2,3]
†$P<0.05$; P value obtained through nominal statistical testing.[2,3]
‡Mixed=67% bDMARD-naive & 33% bDMARD-IR.[3]

DATA LIMITATIONS[2,3]

Data labeled as a primary or ranked secondary endpoint at Week 14 were multiplicity controlled for comparison. All other comparisons were not adjusted for multiplicity; therefore, statistical significance has not been established.

SELECT-AXIS 2 STUDY 1: AS DESIGN INTRO[2]

A 14-week, double-blind, parallel-group, placebo-controlled Phase 3 study of 420 patients with active AS who had an intolerance or inadequate response to at least 2 NSAIDs and 1 or 2 bDMARDs. Patients were randomized to receive RINVOQ 15 mg once daily or placebo. Patients could continue background NSAIDs.

SELECT-AXIS 2 STUDY 2: nr-axSpA DESIGN INTRO[3]

A 52-week, double-blind, placebo-controlled Phase 3 study of 313 patients[a] with nr-axSpA and 1 objective sign of active inflammation based on MRI of the sacroiliac joints and/or hs-CRP greater than the upper limit of normal (ULN; 2.87 mg/L). Patients had an intolerance or inadequate response to at least 2 NSAIDs and, in 33%, to 1 bDMARD. Patients were randomized to receive RINVOQ 15 mg once daily or placebo. Patients could continue background NSAIDs.

[a]314 patients were enrolled, and 313 patients received study drug.

hs-CRP=high sensitivity C-reactive protein; MRI=magnetic resonance imaging; NRI-MI=nonresponder imputation incorporating multiple imputation; NSAID=nonsteroidal anti-inflammatory drug.

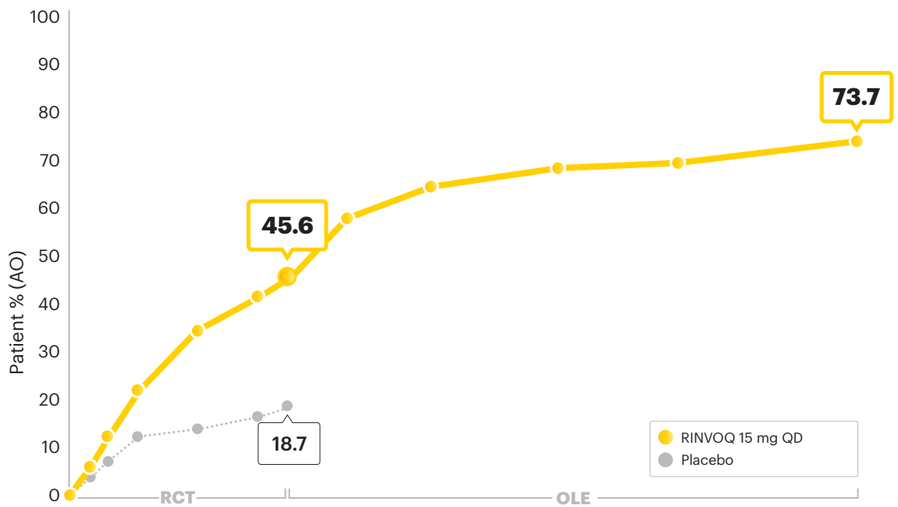
DURABLE ASAS40 RESPONSE RATES[1-5]

RINVOQ® upadacitinib

SELECT-AXIS 2: ASAS40 Response up to Week 52[1-5]

ALL DATA ARE OBSERVED CASES

STUDY 1: AS (bDMARD-IR)



RINVOQ (n=211)
Placebo (n=209)

RINVOQ (n=206)
Placebo (n=203)

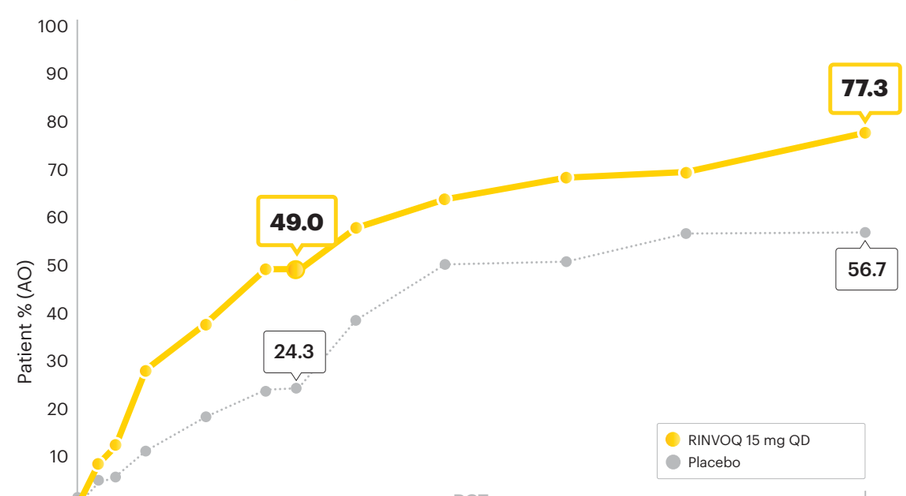
RINVOQ (n=194)

73.7%
of RINVOQ AS patients achieved ASAS40 at 1 year

Time (weeks)

RINVOQ is indicated for TNFi-IR patients

STUDY 2: nr-axSpA (mixed*)



RINVOQ (n=156)
Placebo (n=157)

RINVOQ (n=143)
Placebo (n=148)

RINVOQ (n=132)
Placebo (n=134)

77.3%
of RINVOQ nr-axSpA patients achieved ASAS40 at 1 year

Time (weeks)

RINVOQ is indicated for TNFi-IR patients

*Mixed=67% bDMARD-naive and 33% bDMARD-IR.[3]

ASAS DOMAINS:[2,3]

ASAS40 is defined as at least 40% improvement and an absolute improvement from baseline of ≥2 units on a scale of 0 to 10 in at least 3 of the following 4 domains, with no worsening in the fourth domain:

- Patient Global Assessment of disease activity
- Total back pain, defined on a numeric rating scale (0-10) based on the question, "What is the amount of back pain that you experienced at any time during the last week?"
- Physical function (assessed by BASFI)
- Inflammation (Morning Stiffness) (mean of BASDAI questions 5 and 6 on severity and duration of morning stiffness)

DATA LIMITATIONS:

In an **As Observed (AO)** analysis, patients with missing data at a specific time are not included, which may enrich the population and increase the response rates.

There is potential for enrichment of OLE data; unblinding patients may cause bias related to overall treatment effect.

SAFETY CONSIDERATIONS[1]

Serious Infections: RINVOQ-treated patients are at increased risk of serious bacterial (including tuberculosis [TB]), fungal, viral, and opportunistic infections leading to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants, such as methotrexate or corticosteroids.

Mortality: A higher rate of all-cause mortality, including sudden cardiovascular (CV) death, was observed with a Janus kinase inhibitor (JAKi) in a study comparing another JAKi with tumor necrosis factor (TNF) blockers in rheumatoid arthritis (RA) patients ≥50 years with ≥1 CV risk factor.

Malignancies: Malignancies have occurred in RINVOQ-treated patients. A higher rate of lymphomas and lung cancer (in current or past smokers) was observed with another JAKi when compared with TNF blockers in RA patients.

Major Adverse Cardiovascular Events: A higher rate of CV death, myocardial infarction, and stroke was observed with a JAKi in a study comparing another JAKi with TNF blockers in RA patients ≥50 years with ≥1 CV risk factor. History of smoking increases risk.

BASDAI=Bath Ankylosing Spondylitis Disease Activity Index; BASFI=Bath Ankylosing Spondylitis Functional Index; NRI-MI=nonresponder imputation with multiple imputations; NRS=numeric rating scale; QD=once per day.

SAFETY CONSIDERATIONS[1] (CONTINUED)

Thrombosis: Deep venous thrombosis, pulmonary embolism, and arterial thrombosis have occurred in patients treated with JAK inhibitors used to treat inflammatory conditions. A higher rate of thrombosis was observed with another JAKi when compared with TNF blockers in RA patients.

Hypersensitivity: RINVOQ is contraindicated in patients with hypersensitivity to RINVOQ or its excipients.

Other Serious Adverse Reactions: Hypersensitivity Reactions, Gastrointestinal Perforations, Laboratory Abnormalities, and Embryo-Fetal Toxicity.

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DURABLE ASDAS-LOW DISEASE ACTIVITY RATES[2-5]

RINVOQ® upadacitinib

SELECT-AXIS 2: ASDAS-CRP Low Disease Activity (LDA) up to Week 52[2-5]

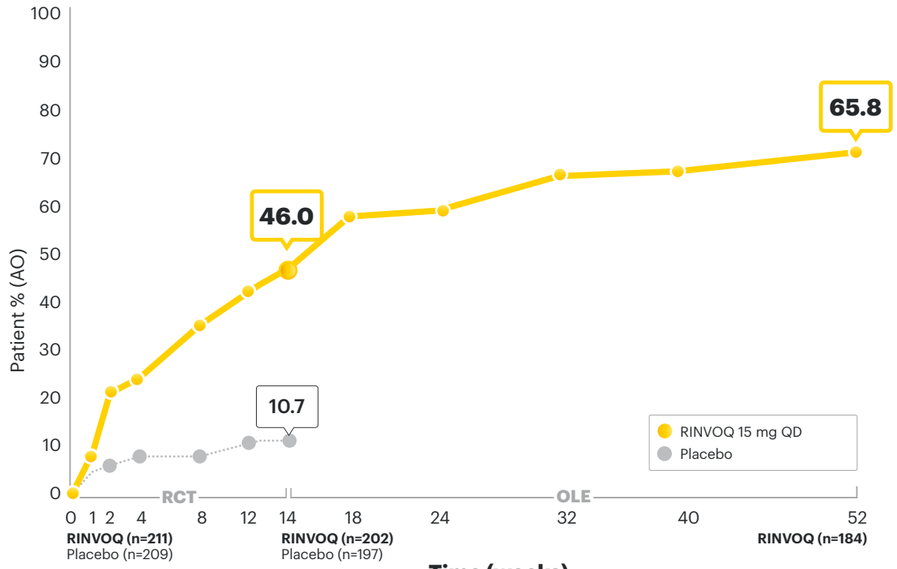
ALL DATA ARE OBSERVED CASES

DATA LIMITATIONS:

In an **As Observed (AO)** analysis, patients with missing data at a specific time are not included, which may enrich the population and increase the response rates.

There is potential for enrichment of OLE data; unblinding patients may cause bias related to overall treatment effect.

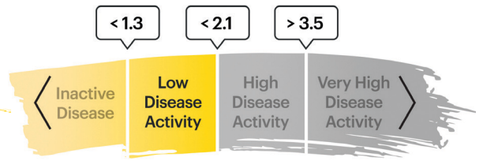
STUDY 1: AS (bDMARD-IR)



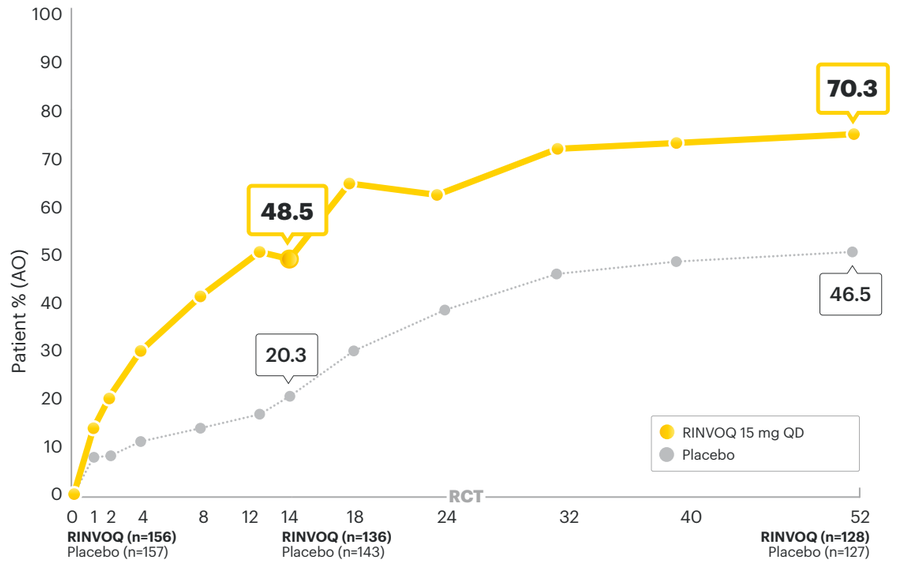
65.8%
of RINVOQ AS patients achieved Low Disease Activity at 1 year

RINVOQ is indicated for TNFi-IR patients

ASDAS Disease Activity States[6]



STUDY 2: nr-axSpA (mixed)*



70.3%
of RINVOQ nr-axSpA patients achieved Low Disease Activity at 1 year

RINVOQ is indicated for TNFi-IR patients

*Mixed=67% bDMARD-naive and 33% bDMARD-IR.[3]

ASDAS-CRP Score[2,3]	AS Patients: Placebo (n=209)	AS Patients: **RINVOQ (n=211)**	nr-axSpA Patients: Placebo (n=156)	nr-axSpA Patients: **RINVOQ (n=154)**
Mean baseline	3.9	**3.9**	3.7	**3.6**
Change in baseline at Week 14 (MMRM) (Ranked Secondary Endpoint)	−0.49	**−1.52**	−0.71	**−1.36**
Change in baseline at Week 52 (MMRM)	−1.93	**−2.00**	−1.23	**−1.80**

SAFETY CONSIDERATIONS[1]

Serious Infections: RINVOQ-treated patients are at increased risk of serious bacterial (including tuberculosis [TB]), fungal, viral, and opportunistic infections leading to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants, such as methotrexate or corticosteroids.

Mortality: A higher rate of all-cause mortality, including sudden cardiovascular (CV) death, was observed with a Janus kinase inhibitor (JAKi) in a study comparing another JAKi with tumor necrosis factor (TNF) blockers in rheumatoid arthritis (RA) patients ≥50 years with ≥1 CV risk factor.

Malignancies: Malignancies have occurred in RINVOQ-treated patients. A higher rate of lymphomas and lung cancer (in current or past smokers) was observed with another JAKi when compared with TNF blockers in RA patients.

Major Adverse Cardiovascular Events: A higher rate of CV death, myocardial infarction, and stroke was observed with a JAKi in a study comparing another JAKi with TNF blockers in RA patients ≥50 years with ≥1 CV risk factor. History of smoking increases risk.

ASDAS=Ankylosing Spondylitis Disease Activity Score; CRP=C-reactive protein.

SAFETY CONSIDERATIONS[1] (CONTINUED)

Thrombosis: Deep venous thrombosis, pulmonary embolism, and arterial thrombosis have occurred in patients treated with JAK inhibitors used to treat inflammatory conditions. A higher rate of thrombosis was observed with another JAKi when compared with TNF blockers in RA patients.

Hypersensitivity: RINVOQ is contraindicated in patients with hypersensitivity to RINVOQ or its excipients.

Other Serious Adverse Reactions: Hypersensitivity Reactions, Gastrointestinal Perforations, Laboratory Abnormalities, and Embryo-Fetal Toxicity.

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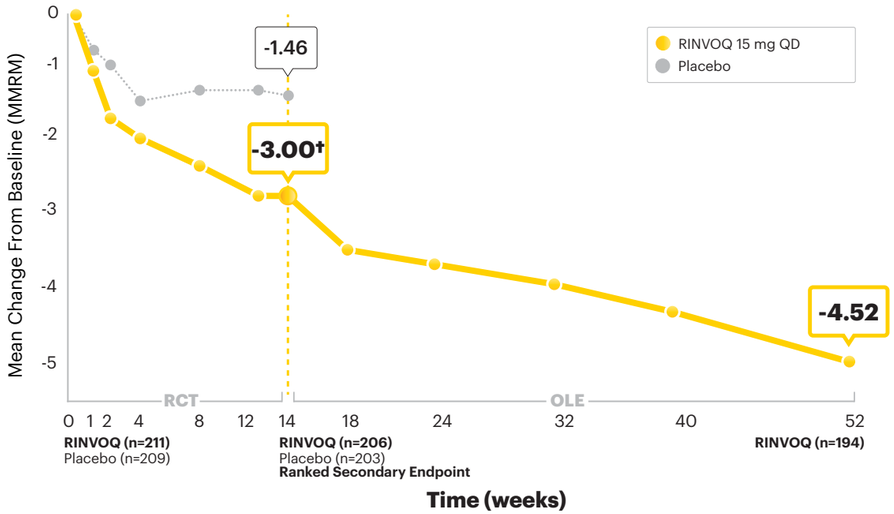
IMPROVEMENT IN TOTAL BACK PAIN[2-5]

Δ Total Back Pain ranked secondary endpoint at Week 14 with response rates up to 1 year[2,3]

RINVOQ® upadacitinib

SELECT-AXIS 2: Δ Total Back Pain from baseline up to Week 52, MMRM[2-5*]

STUDY 1: AS (bDMARD-IR)



Mean baseline in AS patients	Placebo	RINVOQ
	7.39	**7.45**

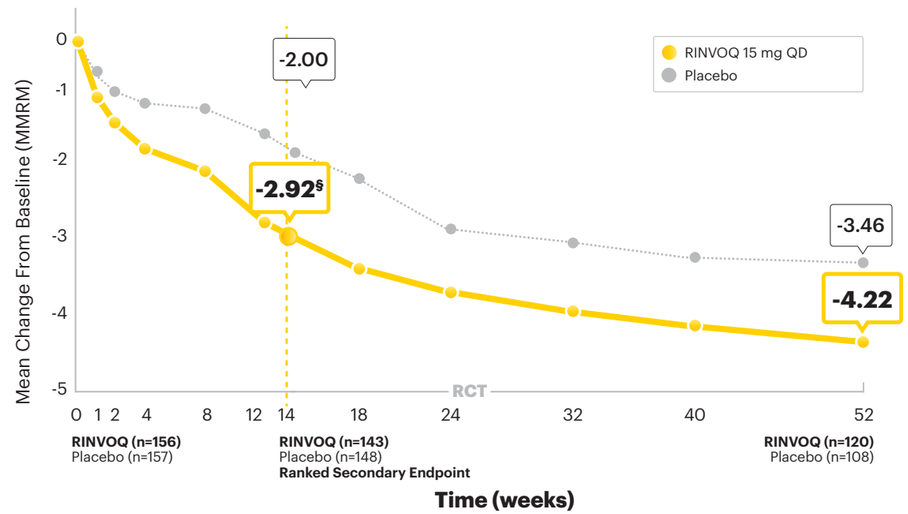
39% **improvement** (n=206) at **Week 14** as observed

and

61% **improvement** (n=194) at **1 year** as observed[7]

RINVOQ is indicated for TNFi-IR patients

STUDY 2: nr-axSpA (mixed‡)



Mean baseline in nr-axSpA patients	Placebo	RINVOQ
	7.29	**7.23**

41% **improvement** (n=143) at **Week 14** as observed

and

59% **improvement** (n=132) at **1 year** as observed[8]

RINVOQ is indicated for TNFi-IR patients

‡Mixed=67% bDMARD-naive and 33% bDMARD-IR.[3] §$P \leq 0.001$.[3]

DATA LIMITATIONS[2,3]:

Data labeled as a ranked secondary endpoint at Week 14 were multiplicity controlled for comparison. All other comparisons were not adjusted for multiplicity; therefore, statistical significance has not been established.

*As a domain of the ASAS40 assessment, total back pain is defined on a numeric rating scale (0-10) based on the following question: "What is the amount of back pain that you experienced at any time during the last week?"[3]

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Serious Infections: RINVOQ-treated patients are at increased risk of serious bacterial (including tuberculosis [TB]), fungal, viral, and opportunistic infections leading to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants, such as methotrexate or corticosteroids.

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Major Adverse Cardiovascular Events: A higher rate of CV death, myocardial infarction, and stroke was observed with a JAKi in a study comparing another JAKi with TNF blockers in RA patients ≥50 years with ≥1 CV risk factor. History of smoking increases risk.

MMRM=mixed-effect model for repeated measures. †$P<0.0001$.[2]

SAFETY CONSIDERATIONS[1] (CONTINUED)

Thrombosis: Deep venous thrombosis, pulmonary embolism, and arterial thrombosis have occurred in patients treated with JAK inhibitors used to treat inflammatory conditions. A higher rate of thrombosis was observed with another JAKi when compared with TNF blockers in RA patients.

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SAFETY PROFILE IN AS & NR-AXSPA[9,10]

RINVOQ® upadacitinib

SELECT-AXIS 2: Safety Profile in AS and nr-axSpA at Week 52[9,10]

Data as of May 19, 2022

TEAE of special interest[a] (E/100 PYs)	AS (SELECT-AXIS 2 Study 1) Any RINVOQ 15 mg QD N=414 PYs=534.4	Nr-axSpA (SELECT-AXIS 2 Study 2) Placebo N=157 PYs=140.2	Nr-axSpA (SELECT-AXIS 2 Study 2) Any RINVOQ 15 mg QD N=156 PYs=137.4
Infections			
Serious infections	**4.5**	0.7	**1.5**
Active tuberculosis	**0**	0	**0**
Opportunistic infection (excluding TB, herpes zoster)	**0**	0	**0**
Herpes zoster	**3.6**	0.7	**3.6**
Malignancy			
Malignancy (excluding NMSC)	**0.2**	0	**0**
Lymphoma	**0.2**	0	**0.7**
NMSC	**0.4**	0.7	**0**
Cardiovascular events			
Adjudicated VTE[b]	**0.4**	1.4	**0**
Adjudicated MACE[c]	**0.2**	0	**0**
Gastroenterological events			
Adjudicated GI perforations	**0**	0	**0**

[a]TEAE: treatment-emergent adverse event, defined as an adverse event with onset on or after first dose of study drug and up to 30 days after last dose of RINVOQ. [b]VTE: venous thromboembolic events, including deep vein thrombosis and pulmonary embolism (fatal and nonfatal). [c]MACE: major adverse cardiovascular events, defined as cardiovascular death, myocardial infarction, and stroke. E/100 PYs=events per 100 patient-years; GI=gastrointestinal; NMSC=nonmelanoma skin cancer; TB=tuberculosis.

Adverse reaction rates observed in clinical trials may not fully characterize the risks of RINVOQ. Certain adverse events may require longer observation periods and longer-term patient exposure to ascertain risk.

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RINVOQ, a once-daily pill: 1st & only JAKi approved for both AS & nr-axSpA

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 varicella zoster or prophylactic 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.

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.

References: 1. RINVOQ [package insert]. North Chicago, IL: AbbVie Inc. **2.** van der Heijde D, Baraliakos X, Sieper J, et al. Efficacy and safety of upadacitinib for active ankylosing spondylitis refractory to biological therapy: a double-blind, randomised, placebo-controlled phase 3 trial. *Ann Rheum Dis*. 2022;81:1515-1523. doi:10.1136/ard-2022-222608 **3.** Deodhar A, Van den Bosch F, Poddubnyy D, et al. Upadacitinib for the treatment of non-radiographic axial spondyloarthritis (SELECT-AXIS 2): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2022;400:369-379. doi:10.1016/S0140-6736(22)01212-0 **4.** Data on file, AbbVie Inc. ABVRRTI75043. **5.** Data on file, AbbVie Inc. ABVRRTI75042. **6.** Machado PM, Raychaudhuri SP. Disease activity measurements and monitoring in psoriatic arthritis and axial spondyloarthritis. *Best Pract Res Clin Rheumatol*. 2014;28(5):711-728. doi:10.1016/j.berh.2014.10.004 **7.** Data on file, AbbVie Inc. ABVRRTI75181. **8.** Data on file, AbbVie Inc. ABVRRTI75182. **9.** Data on file, AbbVie Inc. ABVRRTI74951. **10.** Data on file, AbbVie Inc. ABVRRTI74952. **11.** Data on file, AbbVie Inc. June 2023.

For adult TNFi-IR patients with moderate to severe rheumatoid arthritis (RA), active psoriatic arthritis (PsA), active ankylosing spondylitis (AS), or active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.[1]

CONFIDENCE IN ACCESS & SUPPORT WITH RINVOQ COMPLETE

Available to Prescribe for Your RINVOQ-Ready Patients

FOR RA, PSA, AS, & NR-AXSPA EXCEPTIONAL ACCESS IS ALREADY HERE

>95%
PREFERRED COMMERCIAL AND MEDICARE PART D COVERAGE[11,a,b]

National Commercial and Medicare Part D formulary coverage under the pharmacy benefit as of June 2023.

PAYERS COVER RINVOQ AFTER THE TRIAL OF

1 TNFi

Encourage Your Patients to Enroll in RINVOQ® COMPLETE

PATIENTS CAN ENROLL ONLINE AT RINVOQ.COM/SIGNUP

Affordability
Eligible commercially insured patients may pay as little as $5 per month[c]

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No charge for eligible patients experiencing initial insurance delay or denial for up to 24 months[d]

Support
Exceptional 1:1 patient experience when your patients enroll in RINVOQ Complete

[a]RINVOQ is on a preferred tier or otherwise has preferred status on the plan's formulary. [b]Coverage requirements and benefit designs vary by payer and may change over time. Please consult with payers directly for the most current reimbursement policies. [c]**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/.[d]**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.

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

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

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