# RINVOQ® COMPLETE

**Faxing Instructions:**
Fax to RINVOQ Complete **(1.678.727.0690)**

## Enrollment and Prescription Form

RD-093023-AP09

**The health care professional (HCP) and the patient or legal guardian should fill out this form completely before leaving the office.**
Sections in **GOLD** (1,2,3,4) are necessary for enrollment into RINVOQ Complete. Required fields are marked with an asterisk (*).

### 1 PATIENT'S INFORMATION Please print clearly.

First Name*: Tyler Last Name*: Smith Date of Birth (MM/DD/YYYY)*: 2/14/1989 Gender*: (check one) ☒M ☐F

Name of Patient's Legal Guardian*: Relationship to Patient: ☐Spanish interpreter needed

Patient or Legal Guardian's Address*: 7810 Frankford Ave, Apt. 2B City*: Philadelphia State*: PA ZIP*: 19136

Patient or Guardian's Mobile Phone*: (214)867-5309 Patient or Legal Guardian's Email Address*: tsmith247@gmail.com

When did the patient start on treatment?* ☒Not Yet Started ☐0-3 Months Ago ☐4-6 Months Ago ☐7-12 Months Ago ☐Over 12 Months Ago

▶ ☒ I consent to receive Complete Treatment Support automated and recurring text messages from "AbbVie", including services updates and marketing messages, refill reminders and prescription notifications to the above mobile number. Message and data rates may apply. I am not required to consent as a condition of receiving goods or services. I can reply HELP for help. I can reply STOP to opt out at any time. View privacy notice at **https://privacy.abbvie/privacy-policies/us-privacy-policy.html** and mobile T&C at **https://abbv.ie/USMobileTerms**

By enrolling, you may receive your own Nurse Ambassador provided by AbbVie. Ambassadors do not work under the direction of your health care professional (HCP) or give medical advice. They are trained to direct patients to their HCP for treatment-related advice, including further referrals.

▶ ☒ I consent to the collection, use, and disclosure of my health-related personal data to receive communications from AbbVie regarding its products, programs, services, clinical trials, research opportunities and for online targeted advertising, as further described in the **"How we may use Personal Data," "How we disclose Personal Data,"** and **"Cookies and similar tracking and data collection technologies"** sections of our **Privacy Notice**. My consent is required to process sensitive personal data under certain privacy laws, and I have the right to withdraw my consent by visiting **"Your Privacy Choices"** on AbbVie's website.

For information on how we collect and process your personal data, including the categories we collect, purposes for their collection, and disclosures to third parties, visit **https://abbv.ie/PrivacyPatient**
Through my submission of the RINVOQ Complete Enrollment and Prescription Form, I consent to the collection, use, and disclosure of my personal health data, as described in the Privacy Notice above and in AbbVie's Privacy Notice in the **"How We May Disclose Personal Data"** section. My consent is required to process sensitive personal data under certain privacy laws, and I have the right to withdraw my consent by visiting **"Your Privacy Choices"** on AbbVie's website.

### 2 INSURANCE INFORMATION Please attach insurance and Prescription Insurance cards if available.

**▼ FOR HEALTH CARE PROVIDER USE ONLY ▼**

### 3 DIAGNOSIS*

☒Moderate to Severe Atopic Dermatitis (AD) Date of Diagnosis: 5/1/2022

### 4 PRESCRIBER INFORMATION

I would like to receive a copy: ☐**Benefits Verification Summary** ☐Prior Authorization Form

Prescriber's Name (First, Last)*: John Clark
NPI #*: 31415926535
Office Phone*: 1-800-DERMDOC
Office Contact Name*: Debbie Derma, RPN
Office Fax*: 1-800-DERMFAX
Address*: 1500 Walnut St #007
City*: Philidelphia
State*: PA ZIP*: 19102

### 5 CLINICAL INFORMATION

Fax any necessary clinical/office notes to the preferred Specialty Pharmacy only.

Prior Therapies (select all that apply): ☒Topical Corticosteroid ☐Topical Calcineurin Inhibitor
☐Immunosuppressant (e.g., methotrexate, cyclosporine, etc.) ☒Oral Corticosteroid (e.g., prednisone, etc.)
☐Biologics (e.g., Dupixent, Adbry, etc.) ☐Oral JAK Inhibitors (e.g., Cibinqo, etc.)

Weight: _____

TB Test Date: 10/11/2023 ☐Pos ☒Neg

### 6 PHARMACY PRESCRIPTION - (Optional) Fill out and sign corresponding prescription below.

**Patient's preferred Specialty Pharmacy:** ABC Specialty Pharmacy ☒Check if faxed to Specialty Pharmacy

☒RINVOQ 15 mg extended-release tablets
1 tablet (15 mg) p.o. once daily

☐RINVOQ 30 mg† extended-release tablets
1 tablet (30 mg) p.o. once daily

†Only for AD patients 12 to <65 years weighing at least 40 kgs, who had an inadequate response to 15 mg once daily and who are not taking strong CYP3A4 inhibitors and do not have severe renal impairment. Discontinue RINVOQ if an adequate response is not achieved with the 30 mg dose. Use the lowest effective dose needed to maintain response.

Quantity: ☒30 ☐90
Refills: 3

**PRESCRIBER CERTIFICATION:** I certify that the above therapy is medically necessary and that the information provided is accurate to the best of my knowledge. I certify that I am the prescriber who has prescribed RINVOQ to the previously identified patient and that I provided the patient with a description of the RINVOQ Complete patient support program. I authorize RINVOQ Complete to act on my behalf for the purposes of transmitting this prescription to the appropriate pharmacy designated by the patient utilizing their benefit plan (if applicable).

**Prescriber's Signature: (REQUIRED)*** X John Clark **Date*:** 11/1/2023

### 7 RINVOQ COMPLETE PRESCRIPTION - Required in the event a patient experiences an insurance delay or denial

Eligible patients must have (1) commercial insurance, (2) a valid Rx for RINVOQ, and (3) experienced a delay or denial in insurance determination.
See program Terms and Conditions on the following page. Please complete the full form as well as this section and sign below.
**Prescription to be filled through an AbbVie-authorized pharmacy.** I understand that faxing this form to RINVOQ Complete will result in an original copy being simultaneously transmitted to the AbbVie-authorized pharmacy under this section.

☒RINVOQ 15 mg extended-release tablets
1 tablet (15 mg) p.o. once daily

☐RINVOQ 30 mg† extended-release tablets
1 tablet (30 mg) p.o. once daily

†Only for AD patients 12 to <65 years weighing at least 40 kgs, who had an inadequate response to 15 mg once daily and who are not taking strong CYP3A4 inhibitors and do not have severe renal impairment. Discontinue RINVOQ if an adequate response is not achieved with the 30 mg dose. Use the lowest effective dose needed to maintain response.

Quantity: 30
Refills: _____

**PRESCRIBER CERTIFICATION:** I certify that the above therapy is medically necessary and that the information provided is accurate to the best of my knowledge. I certify that I am the prescriber who has prescribed RINVOQ to the previously identified patient and that I provided the patient with a description of the RINVOQ Complete patient support program. I authorize RINVOQ Complete to act on my behalf for the purposes of transmitting this prescription to the appropriate pharmacy. I understand that the no charge resource through RINVOQ Complete may support patients who are experiencing a delay in insurance coverage for RINVOQ until coverage is obtained, and I confirm that I will support the above-identified patient in seeking to secure such coverage as I deem appropriate. I certify that I will not seek reimbursement from any third party payor for any no charge product dispensed by an AbbVie authorized pharmacy.

**Prescriber's Signature: (REQUIRED)*** X John Clark **Date*:** 1/19/2023

For information on how we collect and process your personal data, including the categories we collect, purposes for their collection, and disclosures to third parties, visit https://abbv.ie/PrivacyHCP
Through my submission of the RINVOQ Complete Enrollment and Prescription Form, I consent to the collection, use, and disclosure of my personal health data, as described in the Privacy Notice above and in AbbVie's Privacy Notice in the "How We May Disclose Personal Data" section. My consent is required to process sensitive personal data under certain privacy laws, and I have the right to withdraw my consent by visiting "Your Privacy Choices" on AbbVie's website.

**Please see Indication and Important Safety Information, including BOXED WARNING on Serious Infections, Mortality, Malignancies, Major Adverse Cardiovascular Events, and Thrombosis, on next page.**
**Please see full Prescribing Information.**

US-RNQD-230436

RINVOQ® upadacitinib

FOR REFERENCE PURPOSES ONLY

# INDICATION AND IMPORTANT SAFETY INFORMATION[1]

## 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 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.

### RINVOQ Complete Prescription Terms and Conditions

**Eligibility criteria:** Available to patients aged 63 or younger with commercial insurance coverage. Patients must have a valid prescription for RINVOQ® (upadacitinib) 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® (upadacitinib) 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.

**Reference: 1.** RINVOQ [package insert]. North Chicago, IL: AbbVie Inc.

**Please see full Prescribing Information.**

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RINVOQ® upadacitinib