



PRESS RELEASE

AbbVie announces registration of RINVOQ® (upadacitinib) for another type of arthritis

SYDNEY AUSTRALIA, 11th January 2023 - AbbVie (NYSE: ABBV) today announced that RINVOQ® (upadacitinib) has been registered in Australia as an oral treatment for adults with active non-radiographic axial spondyloarthritis (nr-axSpA) who have responded inadequately to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs) (see below for full indication).¹

Approximately 30,000 Australians have nr-axSpA, a type of arthritis that mainly affects the pelvis and spine. While symptoms vary for each person, they tend to include stiffness and pain in the back, buttocks, tendons and ligaments and begin between the ages of 15 and 40 years.²

Early diagnosis is important for effective management of symptoms to help people lead active lives. The condition is described as non-radiographic because the inflammation experienced by patients is not able to be seen on an X-ray and therefore diagnosis is generally informed by blood tests and magnetic resonance imaging (MRI).²

Nathalie McNeil, General Manager, AbbVie Australia, welcomed the registration of RINVOQ for nr-axSpA saying, “For many years, AbbVie has worked to transform the impact rheumatic diseases have on the lives of patients. While no cure exists for nr-axSpA, we are proud to be able to provide a new treatment option to help patients living with this condition.

“We will continue working with government stakeholders to ensure timely access via the Pharmaceutical Benefits Scheme.”

Currently RINVOQ is listed on the Pharmaceutical Benefits Scheme (PBS) for severe active rheumatoid arthritis, chronic severe atopic dermatitis, severe psoriatic arthritis and active ankylosing spondylitis (refer to the PBS schedule for full information)³. RINVOQ is not currently listed on the PBS for ulcerative colitis and nr-axSpA.

Important RINVOQ® safety information^{1,4}

Therapy with RINVOQ should be initiated and monitored by a specialist physician well versed in the use of immunomodulatory therapeutic agents like RINVOQ, with expertise in the management of non-radiographic axial spondyloarthritis.

RINVOQ must not be used if the patient has an allergy to upadacitinib or any of its other ingredients, or if the patient has an active, serious infection. In addition, RINVOQ must not be used in combination with biologic disease-modifying anti-rheumatic drugs such as adalimumab or etanercept.

Before using RINVOQ, patients should be checked for current or previous exposure to tuberculosis (TB) infection. RINVOQ should not be given to patients with active TB. TB treatment may be required for patients with TB or have risks of having contracted TB.

Before initiating therapy with RINVOQ, completion of all appropriate immunisations should be considered according to current immunisation guidelines. However, RINVOQ should not be used with live vaccines. Patients should check this with the doctor.

Patients should tell their doctor if they currently have an infection, have had an infection that keeps coming back, have had herpes zoster infection, have had chickenpox, any liver problems (like hepatitis), any heart problems, any cancers, or blood clots.

RINVOQ should be used with caution when certain other medications are being taken. Patients must inform their doctor if they are taking any other medications, including any they obtain without a prescription. In addition, patients must tell their doctor if they have any kidney problems.

Patients should also advise their HCP if they have unexplained stomach (abdominal) pain, have had diverticulitis (painful inflammation of small pockets in the lining of the intestine), or ulcers in the stomach previously.

Some common side effects include acne, upper respiratory tract infections, nose or throat infections, shingles infection, nausea, abnormal blood tests such as high liver enzyme, blood creatine phosphokinase or cholesterol level increases or decreased neutrophil counts, headache, cough, fever, stomach discomfort, and weight gain.

RINVOQ should not be used during pregnancy or breastfeeding.



For further safety information on RINVOQ® please review the Consumer Medicines Information [here](#) (for consumers) or the Product Information [here](#) for healthcare professionals.

ABOUT RINVOQ®

RINVOQ contains the active ingredient upadacitinib, which is a Janus Kinase (JAK) inhibitor. JAK enzymes create signals in the body's immune system that result in inflammation. RINVOQ works to block these signals, thereby reducing inflammation and the production of immune cells within the body.⁴

RINVOQ is used to treat:

- Moderate to severe, active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to, one or more disease-modifying anti-rheumatic drugs (DMARDs). RINVOQ may be used as monotherapy or in combination with methotrexate or other conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs)¹.
- Moderate to severe active psoriatic arthritis in adult patients who have responded inadequately to or are intolerant to one or more DMARDs. RINVOQ may be used as monotherapy or in combination with a non-biological DMARD¹.
- Adults with active ankylosing spondylitis¹.
- Adults and adolescents aged 12 years and above who weigh at least 40 kg for the treatment of moderate to severe atopic dermatitis which is inadequately controlled with active topical pharmacotherapies and for whom systemic therapy is indicated¹.
- Adults with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biological medicine¹.
- Adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) change, who have responded inadequately to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs).¹

About AbbVie in Rheumatology

For more than 20 years, AbbVie has been dedicated to improving care for people living with rheumatic diseases. Our longstanding commitment to discovering and delivering transformative therapies is underscored by our pursuit of cutting-edge science that improves our understanding of promising new pathways and targets in order to help more people living with rheumatic diseases reach their treatment goals.

About AbbVie

AbbVie's mission is to discover and deliver innovative medicines that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's lives across several key therapeutic areas: immunology, oncology, neuroscience, eye care, in addition to products and services across its Allergan Aesthetics

portfolio. For more information about AbbVie, please visit us at www.abbvie.com.au. Follow [@abbvie_AU](#) on Twitter, [Facebook](#), [Instagram](#) or our [LinkedIn](#) page.

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References:

¹ RINVOQ Approved Product Information. <https://apps.medicines.org.au/files/veprinvo.pdf>. Accessed January 2023

² Arthritis Australia. Non-radiographic Axial Spondyloarthritis. <https://arthritisaustralia.com.au/types-of-arthritis/non-radiographic-axial-spondyloarthritis/> Accessed January 2023

³ The Pharmaceutical Benefits Scheme: Upadacitinib <https://www.pbs.gov.au/medicine/item/11979l-11989b>. Accessed September 2022.

⁴ RINVOQ Consumer Medicine Information <https://apps.medicines.org.au/files/vecrinvo.pdf>. Accessed January 2023.