



## PRESS RELEASE

### **AbbVie welcomes the registration of RINVOQ® (upadacitinib) for adult patients with moderately to severely active ulcerative colitis**

**SYDNEY, AUSTRALIA, 28<sup>th</sup> September 2022** - AbbVie (NYSE: ABBV) is pleased to announce that RINVOQ® (upadacitinib) has been registered in Australia for the treatment of adult patients 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 medicine<sup>1</sup>.

According to data from a 2021 study, it is estimated that approximately 85,000 Australians have ulcerative colitis<sup>2,3</sup>. Ulcerative colitis is one of two major types of inflammatory bowel disease<sup>4</sup> (IBD). It can cause inflammation and ulceration in the lining of the large intestine<sup>4</sup>. This can result in people experiencing abdominal pain, frequent diarrhoea, blood in the faeces and feeling generally unwell<sup>5,6</sup>.

Ulcerative colitis is a chronic condition with symptoms that can be unpredictable<sup>5</sup> and affect each person differently<sup>7</sup>. Symptoms may sometimes be particularly active (flare up) and at other times they may be mild and more manageable (remission)<sup>4</sup>. If not managed appropriately, some people with ulcerative colitis may require hospitalisation<sup>5</sup> and eventually surgery<sup>4,5</sup>.

Despite advances in management options in ulcerative colitis, many patients still do not achieve optimal disease control and have an impaired quality of life<sup>8</sup>.

Chris Stemple, Vice President and General Manager of AbbVie Australia and New Zealand, said: "Healthcare services and treatments within the inflammatory bowel disease space have improved over time. However, it's important to continue expanding options for people with IBD. We are delighted to offer eligible Australians living with ulcerative colitis this additional treatment alternative."

The registration of RINVOQ® in ulcerative colitis<sup>9</sup> applies to the following:

- Upadacitinib 15 mg tablet for maintenance dosing (ARTG 312687)
- Upadacitinib 30 mg tablet for maintenance dosing (ARTG 346215)
- Upadacitinib 45 mg tablet for induction dosing (ARTG 375857)

Currently RINVOQ® is listed on the Pharmaceutical Benefits Scheme (PBS) for severe active rheumatoid arthritis, chronic severe atopic dermatitis, severe psoriatic arthritis and ankylosing spondylitis (refer to the PBS schedule for full information)<sup>10</sup>. RINVOQ is not currently listed on the PBS for ulcerative colitis.

## **Important RINVOQ® safety information**<sup>1,10</sup>

Therapy with RINVOQ® should be initiated and monitored by a specialist physician (for example, a gastroenterologist) well versed in the use of immunomodulatory therapeutic agents like RINVOQ, with expertise in the management of the indicated conditions such as ulcerative colitis.

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 immunisation 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, patient must tell their doctor if they have any kidney problems. In these cases, the dosage may need to be modified accordingly.

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® must 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<sup>11</sup>. JAK enzymes create signals in the body's immune system that result in inflammation<sup>10</sup>. RINVOQ works to block these signals, thereby reducing inflammation and the production of immune cells within the body<sup>10</sup>.

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)<sup>1</sup>.
- 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 DMARD<sup>1</sup>.
- Adults with active ankylosing spondylitis<sup>1</sup>.
- 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 indicated<sup>1</sup>.
- 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 medicine<sup>1</sup>.

## 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, virology and gastroenterology, in addition to products and services across its Allergan Aesthetics portfolio. For more information about AbbVie, please visit us at [www.abbvie.com.au](http://www.abbvie.com.au). Follow [@abbvie AU](https://twitter.com/abbvie) on Twitter, [Facebook](https://www.facebook.com/abbvie), [Instagram](https://www.instagram.com/abbvie) or our [LinkedIn](https://www.linkedin.com/company/abbvie) page.

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- <sup>1</sup> RINVOQ approved Product Information <https://apps.medicines.org.au/files/veprinvo.pdf>. Accessed September 2022.
- <sup>2</sup> The [2021 Census](#) counted 25,422,788 people in Australia (excludes overseas visitors).
- <sup>3</sup> Prevalence of inflammatory bowel disease in the Australian general practice population: A cross-sectional study <https://doi.org/10.1371/journal.pone.0252458>. Prevalence of ulcerative colitis in Australia is therefore calculated by  $0.00334 \times 25,422,788 = 84,912$ . Accessed September 2022.
- <sup>4</sup> Crohn's and Colitis Australia: About ulcerative colitis <https://crohnsandcolitis.org.au/about-crohns-colitis/ulcerative-colitis/about-ulcerative-colitis/>. Accessed September 2022.
- <sup>5</sup> Gastroenterological Society of Australia: Clinical update for general practitioners and physicians – inflammatory bowel disease 2018 [https://www.gesa.org.au/public/13/files/Education%20%26%20Resources/Clinical%20Practice%20Resources/IBD/2018 IBD Clinical Update May update.pdf](https://www.gesa.org.au/public/13/files/Education%20%26%20Resources/Clinical%20Practice%20Resources/IBD/2018%20IBD%20Clinical%20Update%20May%20update.pdf). Accessed September 2022.
- <sup>6</sup> Crohn's and Colitis Australia: Ulcerative colitis symptoms <https://crohnsandcolitis.org.au/about-crohns-colitis/ulcerative-colitis/ulcerative-colitis-symptoms/>. Accessed September 2022.
- <sup>7</sup> Crohn's and Colitis Australia: Ulcerative colitis <https://crohnsandcolitis.org.au/about-crohns-colitis/ulcerative-colitis/>. Accessed September 2022.
- <sup>8</sup> Danese S, et al. Unmet medical needs in ulcerative colitis: An expert group consensus <https://www.karger.com/Article/Fulltext/496739>. Accessed September 2022.
- <sup>9</sup> Australian Register of Therapeutic Goods: RINVOQ <https://www.tga.gov.au/resources/artg?keywords=rinvoq>. Accessed September 2022.
- <sup>10</sup> The Pharmaceutical Benefits Scheme: Upadacitinib <https://www.pbs.gov.au/medicine/item/11979I-11989b>. Accessed September 2022.
- <sup>11</sup> RINVOQ Consumer Medicine Information <https://apps.medicines.org.au/files/vecrinvo.pdf>. Accessed September 2022.