

Summary report on authorisation dated 9 March 2026

Rinvoq® (active substance: upadacitinib)

Indication extension in Switzerland: 2 September 2025

Prolonged-release tablets for the treatment of adults with active recurrent giant cell arteritis in combination with a tapering course of corticosteroid therapy

About the medicinal product

Rinvoq contains the active substance upadacitinib.

Rinvoq was authorised by Swissmedic on 20 January 2020 for the treatment of adults with moderate to severe rheumatoid arthritis who do not respond adequately to, or who are unable to tolerate, treatment with one or more synthetic anti-rheumatic medicines.

On 23 March 2021, an indication extension was approved for Rinvoq for the treatment of adults with psoriatic arthritis who do not respond adequately to, or who are unable to tolerate, one or more anti-rheumatic medicines.

Also on 23 March 2021, a further indication extension was approved for Rinvoq for the treatment of adults with active ankylosing spondylitis who do not respond adequately to treatment with other anti-inflammatory medicines.

On 26 November 2021, a further indication extension was approved for Rinvoq for the treatment of adults with moderate to severe

atopic dermatitis when treatment with conventional, locally applied topical medicinal products is unable to control the disease adequately or cannot be used.

A further indication extension was approved on 7 June 2024: Treatment of adults with ulcerative colitis who have responded inadequately, or no longer respond, to at least one biological agent¹, or were unable to tolerate it, or cannot be administered this type of therapy.

Also approved on 7 June 2024 was a further indication extension: Treatment of adults with moderate to severe Crohn's disease who have responded inadequately, or no longer respond, to at least 1 biological agent, or were unable to tolerate it, or for whom such treatment is contraindicated.

The current indication extension means that Rinvoq can now be used in combination with a tapering course of corticosteroid therapy

¹ Biological agent: medication manufactured using biotechnology.

for the treatment of adults with active recurrent giant cell arteritis who require no more than 60 mg prednisone per day.

Giant cell arteritis is an inflammation of the large and medium blood vessels that commonly occurs in people aged over 50. The main symptoms include headache, jaw discomfort and visual symptoms.

Mode of action

Rinvoq inhibits “Janus kinases” (JAK), enzymes that are responsible for signal trans-

mission within cells. As a result of this inhibition, the activity of the JAK in the body is decreased, thereby reducing inflammation.

Administration

Rinvoq is a prescription-only medicine and is authorised as a prolonged-release tablet containing 15 mg, 30 mg, and 45 mg of the active substance upadacitinib.

The recommended dose for the treatment of adults with recurrent giant cell arteritis is 15 mg once daily in combination with a tapering dose of corticosteroids. After the completion of corticosteroid therapy, Rinvoq can be continued as monotherapy.

Rinvoq should be taken at approximately the same time each day. The tablet should be swallowed whole with a glass of water, with or without food. The tablet must not be split, crushed, or chewed before swallowing. Foods or drinks containing grapefruit should be avoided while using Rinvoq as this increases the amount of upadacitinib in the body and, as a consequence, the risk of adverse reactions.

Efficacy

The efficacy of Rinvoq in the treatment of giant cell arteritis was investigated in a study with 428 patients aged 50 and above. The participants were divided into three treatment groups. Two groups received either 15 mg or 7.5 mg Rinvoq, while the third group received a placebo (dummy drug). All patients additionally received a corticosteroid

dose that was gradually reduced to 0 mg, but at different rates: in both Rinvoq groups until week 26, and in the placebo group until week 52. After 52 weeks, it emerged that significantly more patients in the group taking 15 mg Rinvoq remained permanently symptom-free than in the group receiving a placebo.

Precautions, undesirable effects, & risks

Rinvoq may not be used in those who are hypersensitive to the active substance or any of the excipients.

As a result of the mode of action of Rinvoq, the body's own immune system may be inhibited during long-term treatment with this medicinal product. The use of Rinvoq should be avoided in patients with a serious infection. Before starting treatment with Rinvoq, it should be checked whether important vaccinations are up to date. If necessary, these should be given before starting

treatment with Rinvoq. Certain vaccines cannot be administered during treatment with Rinvoq.

The most common (affecting more than 1 in 10 users) short-term undesirable effect was the occurrence of headache.

Rinvoq can cause serious side effects, which the doctor should be informed of immediately (e.g. fever, sweating or chills, shortness of breath, bloody sputum, weight loss, burning sensation on urination, or more frequent need to urinate).

In addition, taking JAK inhibitors such as Rinvoq increases the risk of severe cardiovascular disease, cancers, and general mortality. All precautions, risks, and other possible un-

desirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

Rinvoq offers a new option for the treatment of active recurrent giant cell arteritis in adults who require no more than 60 mg prednisone per day. Studies have shown that the additional treatment with Rinvoq caused more patients to remain permanently symptom-free than those treated with placebo.

Taking all the risks and precautions into account, and based on the available data, the

benefits of Rinvoq outweigh the risks. Swissmedic has therefore authorised the medicinal product Rinvoq with the active substance upadacitinib, in combination with a tapering course of corticosteroid therapy, in Switzerland for the treatment of active recurrent giant cell arteritis.

Further information on the medicinal product

Information for healthcare professionals: [Information for healthcare professionals Rinvoq®](#)

Information for patients (package leaflet): [Information for patients Rinvoq®](#)
Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.