swissmedic

Summary report on authorisation dated 22 November 2024

# Rinvoq® (active substance: upadacitinib)

## Indication extension in Switzerland: 7 June 2024

## Prolonged-release tablets for the treatment of moderate to severe active Crohn's disease in adults

## About the medicinal product

Rinvoq contains the active substance upadacitinib and is used in adult patients with Crohn's disease (CD) who have responded inadequately to or no longer respond to at least one biological agent[1], or were unable to tolerate it, or cannot be administered this type of therapy.

Crohn's disease is a condition that causes inflammation in all parts of the digestive tract, but most frequently the intestines. The inflammation leads to thickening of the intestinal wall and narrowing of the intestinal lumen. Healthy segments of intestine alternate with affected segments. Typical symptoms of CD include abdominal pain, diarrhoea (with or without visible bleeding), fatigue, and weight loss. Symptoms are usually chronic and come and go, but the course of the disease may differ. Some CD patients have a continuous, progressive (active) disease course, while around 20% of CD patients experience a prolonged phase after the initial onset of symptoms during which their MC symptoms are either less pronounced or disappear completely.

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

[1] Biological agent: medication manufactured using biotechnology

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

An indication extension for Rinvoq for the treatment of ulcerative colitis was submitted in parallel with the current authorisation.

## Mode of action

Rinvoq inhibits "Janus kinases" (JAK), enzymes that are responsible for signal transmission 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 starting treatment for CD is 45 mg upadacitinib once daily for 12 weeks. Under certain conditions, the initial treatment can be extended by a further 12 weeks at a dose of 30 mg once daily. If the initial treatment is effective, the subsequent maintenance dose is 15 mg or 30 mg once daily.

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 upadacitinib has been investigated in 3 studies involving patients with moderate to severe active Crohn's disease. The studies showed that Rinvoq led to an improvement in symptoms and/or intestinal inflammation after 12 weeks in more CD patients who had not responded adequately to previous treatment(s) compared to placebo. Long-term treatment with Rinvoq was then investigated compared to placebo for up to 52 weeks in patients who had shown an improvement after the initial 12-week treatment. In these patients, continuation of the treatment with Rinvoq at a reduced dose continued to have a better effect compared to placebo. However, there are uncertainties regarding efficacy in older CD patients (over 65 years) and in patients who had not previously been administered a biological agent.

## 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 short-term undesirable effects in more than 10% of all patients treated with Rinvoq were infections of the upper respiratory tract and the occurrence of acne.

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

## Why the medicinal product has been authorised

The studies conducted show a benefit of Rinvoq versus placebo in the treatment of moderate to severe active Crohn's disease. Several biological agents are currently authorised for the treatment of this disease, but no Janus kinase (JAK) inhibitors. Treatment with a JAK inhibitor, such as Rinvoq, increases the risk of severe cardiovascular disease, cancers, and general mortality. Rinvoq should therefore only be used by CD patients who have undergone at least 1 unsuccessful treatment with a biological agent.

Based on all the available data, the benefits of Rinvoq outweigh the risks if used correctly in appropriately selected patients. Swissmedic has therefore extended the authorisation for use in Switzerland of the medicinal product Rinvoq to include the treatment of adult patients with moderate to severe active Crohn's disease who have responded inadequately to or no longer respond to at least one biological agent, or were unable to tolerate it, or cannot be administered this type of therapy.

## 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.

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