swissmedic

Summary report on authorisation dated 23 December 2024

Rinvoq® (active substance: upadacitinib)

Indication extension in Switzerland: 7 June 2024

Prolonged-release tablets for the treatment of moderate to severe active ulcerative colitis in adults

About the medicinal product

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

Ulcerative colitis is a chronic disease in which the intestinal mucosa, particularly in the rectum, repeatedly becomes inflamed and the inflammation spreads further through the colon. The disease usually occurs for the first time between the ages of 15 and 40 years. Typical symptoms include diarrhoea, often containing blood, frequent bowel movements with small amounts of stool, abdominal pain, a strong urge to defecate, and occasionally faecal incontinence. The inflammation usually begins gradually and gets worse over several weeks. Over the course of the disease, up to 25% of those affected develop symptoms outside of the bowel.

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 1 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, 1 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.

[1] Biological agent: medication manufactured using biotechnology.

An indication extension for Rinvoq for the treatment of Crohn's disease 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.

Use

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 UC is 45 mg upadacitinib once daily for 8 weeks. Under certain conditions, the initial treatment can be extended by a further 8 weeks at a dose of 45 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 Rinvoq was investigated in 2 studies (M14-234 SS2 and M14-675) in which a total of 988 UC patients participated. UC patients who had not had an adequate response to previous treatment(s) received either 45 mg Rinvoq or a placebo (dummy drug) once daily for 8 weeks. Changes in the disease symptoms and bowel inflammation were measured using an evaluation scale.

Disease symptoms improved clearly in the Rinvoq group in both studies (M14-234 SS2: Rinvoq 26.1% vs. placebo 4.8%; M14-675: Rinvoq 33.5% vs. placebo 4.1%).

The efficacy of Rinvoq in subsequent maintenance therapy with 15 mg or 30 mg was demonstrated in a further study (M14-234 SS3) over 52 weeks.

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 efficacy of Rinvoq in moderate to severe active UC was confirmed in studies. After 8 weeks of treatment, symptoms improved in significantly more patients taking the medicinal product than those taking a placebo. Patients in whom other medicinal products (including biological agents) did not work or were not tolerated also responded to the therapy. 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 UC patients who have undergone at least 1 unsuccessful treatment with a biological agent.

Based on all the available data, and when used correctly, the benefits of Rinvoq outweigh the risks. Swissmedic has therefore extended the authorisation for use in Switzerland of the medicinal product Rinvoq, containing the active substance upadacitinib, to include the treatment of adult patients with moderate to severe active ulcerative colitis who have responded inadequately to or no longer respond to at least 1 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.

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.