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# Rinvoq® (active substance: upadacitinib)

## Indication extension in Switzerland: 23.03.2021

## Medicinal product for the treatment of psoriatic arthritis in adults

## About the medicinal product

Rinvoq contains the active substance upadacitinib and is used for the treatment of adults with psoriatic arthritis that cannot be controlled well enough with one or more disease-modifying anti-rheumatic medicines, or if the patient cannot take these medicines.

Psoriatic arthritis (PsA) is a chronic inflammatory joint disease (arthritis) that occurs together with psoriasis. It is also known as arthritis psoriatica.

Rinvoq can be used as monotherapy (as the only medication) or in combination with non-biologic disease-modifying anti-rheumatic medicines.

Rinvoq was authorised by Swissmedic on 20 January 2020 for the treatment of adults with moderate to severe rheumatoid arthritis that cannot be controlled well enough with one or more synthetic disease-modifying anti-rheumatic medicines, or if the patient cannot take these medicines.

## Mode of action

Rinvoq inhibits "Janus kinases", which play a role in psoriatic arthritis (PsA). This reduces pain, stiffness and swelling in and around the joints, pain and stiffness in the spine, psoriatic rash and tiredness, and slows down the damage to the bone and cartilage in the joints.

## Use

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

The recommended dose is 1 tablet 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.

## Efficacy

The efficacy of Rinvoq has been investigated in two studies involving patients with moderate to severe active psoriatic arthritis (studies M15-554 and M15-572). To compare treatment with Rinvoq, some patients in the studies were treated with a placebo (dummy drug). Study M15-572 also investigated the efficacy of Rinvoq compared to a conventional medicinal product containing the active substance adalimumab.

Both studies demonstrated a significant benefit of treatment with Rinvoq versus baseline and compared to treatment with placebo. Rinvoq inhibits structural degradation and improves physical functioning.

No significant differences were observed for treatment with Rinvoq compared to treatment with adalimumab.

## 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 treatment with this medicinal product. Therefore, the use of Rinvoq should be avoided in patients with an active, serious infection. Before starting treatment with Rinvoq, it should be checked whether important vaccinations are up to date and, if necessary, should be given first.

The most common side effects in all patients treated with Rinvoq were infections of the nose and throat.

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

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 medicine has been authorised

Both of the studies conducted show a benefit of Rinvoq versus placebo in the treatment of psoriatic arthritis in adults.

A study directly comparing Rinvoq to a medicinal product already authorised for psoriatic arthritis with the active substance adalimumab does not describe any significant differences in efficacy, safety or tolerance.

Based on all the available data, the benefits of Rinvoq outweigh the risks. Swissmedic has therefore extended the authorisation of the medicinal product Rinvoq for use in Switzerland and authorised the treatment of adult patients with psoriatic arthritis that cannot be controlled well enough with one or more disease-modifying anti-rheumatic medicines, or if the patient cannot take these medicines.

## 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 (doctors, pharmacists and others) 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 Public Summary SwissPAR.

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.