swissmedic

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Rinvoq® (active substance: upadacitinib)

First authorisation in Switzerland: 20.01.2020

Medicine for the treatment of rheumatoid arthritis (RA) in adults

About the medicine

Rinvoq contains the active substance upadacitinib and was authorised by Swissmedic on 20 January 2020 for the treatment of adults with moderate or severe rheumatoid arthritis that cannot be controlled well enough with disease-modifying anti-rheumatic medicines, or if the patient cannot take these medicines. Rinvoq can be used in combination with other anti-rheumatic medicines or as treatment on its own.

Rheumatoid arthritis (RA) is a disease that causes inflammation of the joints.

Mode of action

Rheumatoid arthritis occurs when the body's own immune system damages healthy tissue and causes inflammation in the joints. An enzyme called "Janus kinase" is involved in this inflammatory process.

Rinvoq works by inhibiting the activities of this enzyme in the body, reducing pain, stiffness and swelling in the joints, as well as tiredness, and slowing down the damage to the bone and cartilage in the joints.

Use

Rinvoq is available as a tablet containing a daily dose of 15 mg of the active substance upadacitinib and should be prescribed only by a qualified doctor experienced in diagnosing and treating rheumatoid arthritis. Blood tests may be needed before treatment is started with Rinvoq. These are designed to reduce the risk of problems associated with Rinvoq treatment. Rinvoq can be used in combination with other anti-rheumatic medicines or as treatment on its own.

If serious infections occur during treatment, Rinvoq should be discontinued.

Efficacy

The efficacy of Rinvoq has been investigated in five studies involving patients with moderate or severe active rheumatoid arthritis. Two studies investigated the efficacy of upadacitinib as an active substance on its own. Three studies investigated upadacitinib as a supplement to other anti-rheumatic medicines.

In all studies, the patients who took Rinvoq showed better results during treatment in respect of physical function, health-related results such as pain relief, swollen joints, tenderness, morning stiffness, and the general assessment by the doctor and patient compared to patients who did not take Rinvoq.

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 its mode of action, the body's own immune system may be inhibited during treatment with this medicine.

Therefore, the use of Rinvoq should be avoided in patients with an active, serious infection.

A benefit-risk assessment is required before starting treatment with Rinvoq in the following cases:

- patients with chronic, possible or recurrent infections
- patients with tuberculosis
- patients who have lived in, or visited, regions with tuberculosis or fungal infections
- patients who are prone to infections as a result of an underlying illness.

The most common side effects (in more than 2 %) in all patients treated with Rinvoq were upper respiratory tract infections, nausea, cough and raised levels of creatine phosphokinase* in the blood (*enzyme; a raised level is an indication of damage to the skeletal or heart muscle).

The effect of treatment with Rinvoq on vaccines has not been investigated to any significant extent. In view of the possible inhibition of the immune system, vaccinations with live vaccines should not be used during or immediately before treatment with Rinvoq. Before treatment is started with Rinvoq, it is recommended that patients be brought up to date with all immunisations, including preventive zoster vaccinations, in accordance with the latest immunisation guidelines.

Healthcare professionals can provide information about other possible side effects, precautions and risks, which are listed in the Information for healthcare professionals and the Information for patients (package leaflet).

Why the medicine has been authorised

Based on the study results, Swissmedic concluded that a treatment with Rinvoq on its own or in combination with other anti-rheumatic medicines is beneficial and that the efficacy corresponds with what is expected of an anti-rheumatic medicine. Swissmedic considers that the benefit that can be expected from its correct use outweighs the associated risks. Swissmedic has therefore authorised the medicine Rinvoq with the active substance upadacitinib for use in Switzerland for the above-mentioned indication.

Further information on the medicinal product

Information for healthcare professionals:
Information for healthcare professionals Rinvoq®

Information for patients (package leaflet):
Patient information Rinvoq®

Healthcare professionals (doctors, pharmacists and others) can answer any further questions.

This information is correct as at the date above. New information concerning the authorised medicinal product in question will not be incorporated in the Public Summary SwissPAR.

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