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Rinvoq® (active substance: upadacitinib)

Indication extension in Switzerland: 23.03.2021

Medicinal product for the treatment of ankylosing spondylitis in adults

About the medicinal product

Rinvoq contains the active substance upadacitinib and is used for the treatment of adults with active ankylosing spondylitis that cannot be controlled well enough with other anti-inflammatory medicines.

Ankylosing spondylitis is a disease that primarily causes inflammation in the spine. It is also known as Bekhterev's disease.

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.

On 23 March 2021, Rinvoq was also approved 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.

Mode of action

Rinvoq inhibits "Janus kinases", which play a role in ankylosing spondylitis. This reduces back pain, stiffness and inflammation in the spine.

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 for treatment of ankylosing spondylitis was investigated in a two-phase clinical study (SELECT-AXIS study).

To compare treatment with Rinvoq, one group of patients with ankylosing spondylitis was treated with a placebo (dummy drug) in the first phase of the study in addition to any existing medications. After a treatment duration of 14 weeks with Rinvoq, a significant improvement was found in the functioning of the affected areas of the body compared to the start of treatment and in comparison to treatment with placebo.

In the second phase of the study, all patients were treated with Rinvoq for 90 weeks. The efficacy of Rinvoq was further demonstrated by the improved response in patients previously treated with placebo.

Alongside other endpoints, the improvement in condition or "response rate" was determined based on a general assessment of disease activity by the patients, overall assessment of back pain, inflammation and functioning.

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 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.

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

The study conducted shows a benefit of Rinvoq versus placebo in the treatment of ankylosing spondylitis in adults.

Based on all the available data, the benefits of Rinvoq outweigh the risks in the view of Swissmedic. Swissmedic has therefore extended the authorisation of the medicinal product Rinvoq for use in Switzerland and authorised the treatment of adult patients with ankylosing spondylitis that cannot be controlled well enough with other anti-inflammatory 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.