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Rinvoq® (active substance: upadacitinib)

Indication extension in Switzerland: 26 November 2021

Medicinal product for the treatment of moderate to severe atopic dermatitis (neurodermatitis) in adults

About the medicinal product

Rinvoq contains the active substance upadacitinib and is used for the treatment of adult patients with moderate to severe atopic[1] dermatitis (also known as atopic eczema or neurodermatitis). Dermatitis is an inflammation of the top layers of the skin that usually manifests as a red, very itchy rash. Up to 8% of all adults are affected by atopic dermatitis. Most cases involve mild forms that can be well controlled with locally applied topical products such as skin ointments. But stubborn forms that can require costly treatments with possible severe side effects also exist.
Therefore, Rinvoq is used only when treatment with conventional, locally applied topical medicinal products are unable to control the disease adequately or cannot be used.

Rinvoq has already been 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, Rinvoq was additionally approved 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 drugs.

Also on 23 March 2021, Rinvoq was additionally approved for the treatment of adults with active ankylosing spondylitis who do not respond adequately to treatment with other anti-inflammatory medicines.

[1]Atopy: Atopy refers to an allergic hypersensitivity to otherwise harmless natural and synthetic substances in the environment.

Mode of action

Rinvoq inhibits "Janus kinases", enzymes that are responsible for signal transmission within cells. As a result of this inhibition, the activity of the Janus kinases in the body is decreased, thereby reducing inflammation.

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 in the treatment of atopic dermatitis was investigated in three studies with a total of 2,584 patients with at least moderate disease that was not adequately controlled by topical treatment (studies: MEASURE UP 1, MEASURE UP 2 and AD UP).

In all three studies, the patients received 15 mg or 30 mg Rinvoq or placebo (dummy drug) once a day for a period of 16 weeks.

The severity of dermatitis is determined by scores achieved on rating scales (SCORAD and EASI). The corresponding improvements in the scores are also used to confirm the effect in the clinical trials. All studies showed that treatment with Rinvoq produced a significant improvement in the scores compared to treatment with placebo. A faster improvement in the appearance of the skin and the itching was also achieved.

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.

The most common short-term side effects in all patients treated with Rinvoq were infections of the nose and throat and the occurrence of acne.

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).

Treatment with Rinvoq should be discontinued if no improvement is visible after 12 weeks at the latest.

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 completed studies showed a benefit for Rinvoq, compared to placebo, in the treatment of atopic dermatitis in adults with at least moderate disease that cannot be adequately controlled by local, topical measures.

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 of the medicinal product Rinvoq, for use in Switzerland, to include the treatment of adult patients with at least moderate atopic dermatitis when locally applied topical medicinal products are unable to control the disease adequately or cannot be used.

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 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.