



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/582949/2019  
EMA/H/C/004760

## Rinvoq (*upadacitinib*)

An overview of Rinvoq and why it is authorised in the EU

### What is Rinvoq and what is it used for?

Rinvoq is a medicine for treating adults with rheumatoid arthritis, a disease that causes inflammation of the joints.

Rinvoq is used for 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. It can be used on its own or with methotrexate, another medicine for rheumatoid arthritis.

Rinvoq contains the active substance upadacitinib.

### How is Rinvoq used?

Rinvoq can only be obtained with a prescription. Treatment with the medicine should be started and supervised by a doctor experienced in diagnosing and treating rheumatoid arthritis. It is available as 15 mg tablets.

The recommended dose of Rinvoq is one tablet once a day. The doctor may interrupt treatment in case of certain side effects, including falls in blood cell counts. For more information about using Rinvoq, see the package leaflet or contact your doctor or pharmacist.

### How does Rinvoq work?

In patients with rheumatoid arthritis, the immune system (the body's defences) attacks healthy tissue, causing inflammation in the joints.

Upadacitinib, the active substance in Rinvoq, is an immunosuppressant. This means that it reduces the activity of the immune system. Upadacitinib works by blocking the action of enzymes called Janus kinases. These enzymes are involved in setting up processes that lead to inflammation, and blocking their effect brings inflammation in the joints under control.

---

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

An agency of the European Union



© European Medicines Agency, 2019. Reproduction is authorised provided the source is acknowledged.

Classified as public by the European Medicines Agency

## **What benefits of Rinvoq have been shown in studies?**

Five studies involving a total of nearly 4,400 patients found Rinvoq effective in reducing symptoms in patients with moderate to severe rheumatoid arthritis. These studies involved rating disease activity in 28 joints in the body on a standard scale.

The first study was in patients who had not previously been treated with methotrexate. It found that after 24 weeks, 48% of patients were in remission (clear of symptoms) after treatment with Rinvoq compared with 19% of patients receiving methotrexate.

The second study was in patients whose disease was not well controlled with disease-modifying anti-rheumatic medicines. It found that of patients treated with Rinvoq, 48% had low disease activity after 12 weeks compared with 17% of patients receiving placebo (a dummy treatment).

The third study was in patients whose disease was not controlled well with methotrexate. It found that 45% of patients treated with methotrexate plus Rinvoq had low disease activity after 12 weeks compared with 29% of patients treated with methotrexate plus adalimumab (a biological disease-modifying anti-rheumatic medicine) and 14% of patients receiving methotrexate plus placebo.

The fourth study was also in patients whose disease was not controlled well enough with methotrexate. It found that 45% of the patients treated with Rinvoq on its own had low disease activity after 14 weeks compared with 19% of patients continuing their methotrexate treatment.

The fifth study involved patients for whom a biological disease-modifying anti-rheumatic medicine was either not suitable or did not work well enough. The patients were being treated with conventional disease-modifying anti-rheumatic medicines (chloroquine, hydroxychloroquine, leflunomide or sulfasalazine, often combined with methotrexate). Of the patients who also received Rinvoq, 43% had low disease activity compared with 14% of patients receiving placebo.

## **What are the risks associated with Rinvoq?**

The most common side effects with Rinvoq (which may affect more than 1 in 10 people) are upper respiratory tract infections (nose and throat infections). The most important serious side effects are serious infections. For the full list of side effects of Rinvoq, see the package leaflet.

Rinvoq must not be used in patients with tuberculosis or serious infections. It must also not be used in patients with severe liver problems or during pregnancy. For the full list of restrictions, see the package leaflet.

## **Why is Rinvoq authorised in the EU?**

Rinvoq was effective at controlling moderate to severe rheumatoid arthritis in patients whose disease had not improved enough with other disease-modifying anti-rheumatic medicines. Studies found that it reduced disease activity when used alone or combined with other medicines. Patients treated with Rinvoq may have side effects that include infection, neutropenia (low count of a type of white blood cell), and blood tests that suggest liver or muscle damage and raised blood lipids. However, these side effects are considered manageable.

The European Medicines Agency therefore decided that Rinvoq's benefits are greater than its risks and that it can be authorised for use in the EU.

## **What measures are being taken to ensure the safe and effective use of Rinvoq?**

The company that markets Rinvoq will provide information to healthcare professionals about the risks of infection, harm to the unborn baby if Rinvoq is taken during pregnancy, and problems affecting the heart and circulation. The company will also supply a patient alert card describing warning signs of Rinvoq's serious side effects and how to get help, and a reminder not to use it during pregnancy.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Rinvoq have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Rinvoq are continuously monitored. Side effects reported with Rinvoq are carefully evaluated and any necessary action taken to protect patients.

## **Other information about Rinvoq**

Rinvoq received a marketing authorisation valid throughout the EU on 16 December 2019.

Further information on Rinvoq can be found on the Agency's website:

[ema.europa.eu/medicines/human/EPAR/rinvoq](http://ema.europa.eu/medicines/human/EPAR/rinvoq).

This overview was last updated in 12-2019.