17 October 2019
EMA/CHMP/521392/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Rinvoq

upadacitinib

On 17 October 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Rinvoq, intended for the treatment of rheumatoid arthritis. The applicant for this medicinal product is AbbVie Deutschland GmbH & Co. KG.

Rinvoq will be available as 15-mg prolonged-release tablets. The active substance of Rinvoq is upadacitinib, an immunosuppressant and a selective and reversible JAK inhibitor (ATC code: not yet assigned). Upadacitinib preferentially inhibits signalling by JAK1 or JAK1/3 with functional selectivity over cytokine receptors that signal via pairs of JAK2.

The benefits with Rinvoq are its ability to reduce the symptoms of rheumatoid arthritis. The most common side effects are upper respiratory tract infections, nausea, blood creatine phosphokinase increased and cough. The most common serious adverse reactions are serious infections.

The full indication is: “Rinvoq is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Rinvoq may be used as monotherapy or in combination with methotrexate.”

It is proposed that Rinvoq be prescribed by physicians experienced in the diagnosis and treatment of rheumatoid arthritis.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union