

## Rinvoq<sup>®</sup> (upadacitinib) – New indication

- On April 29, 2025, [AbbVie announced](#) the FDA approval of [Rinvoq \(upadacitinib\)](#), for the **treatment of adults with giant cell arteritis**.
  - Rinvoq is not recommended for use in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine.
- Rinvoq is also approved for the treatment of rheumatoid arthritis, psoriatic arthritis, atopic dermatitis, ulcerative colitis, Crohn's disease, ankylosing spondylitis, non-radiographic axial spondyloarthritis, and polyarticular juvenile idiopathic arthritis.
- Rinvoq is the first JAK inhibitor approved for giant cell arteritis.
- The approval of Rinvoq for the new indication was based on a randomized, double-blind, placebo-controlled study in 428 patients 50 years of age and older with new-onset or relapsing giant cell arteritis. Patients were randomized to Rinvoq 15 mg, upadacitinib 7.5 mg, or placebo. All patients received background corticosteroid therapy. The primary endpoint was the proportion of patients achieving sustained remission at week 52 as defined by the absence of giant cell arteritis signs and symptoms from week 12 through week 52 and adherence to the protocol-defined corticosteroid taper regimen.
  - Sustained remission at week 52 was achieved in 46.4% and 29.0% of patients in the Rinvoq and placebo groups, respectively (difference of 17.1, 95% CI: 6.3, 27.8;  $p \leq 0.01$ ).
- Rinvoq carries a boxed warning for serious infections, mortality, malignancy, major adverse cardiovascular events, and thrombosis.
- The most common adverse reactions ( $\geq 5\%$ ) with Rinvoq use in giant cell arteritis were upper respiratory tract infections, headache, fatigue, peripheral edema, cough, anemia, rash, herpes zoster, and nausea.
- The recommended dose of Rinvoq for the treatment of giant cell arteritis is **15 mg orally once daily** in combination with a tapering course of corticosteroids.
  - Refer to the Rinvoq drug label for dosing for all its other indications.