

Rinvoq® (upadacitinib), Rinvoq LQ (upadacitinib) – New formulation approval, New/expanded indications

- On April 26, 2024, the FDA approved a new oral solution formulation of Novartis' [Rinvoq \(upadacitinib\)](#) (brand name Rinvoq LQ).
 - Rinvoq was previously approved as an oral tablet.
- In addition to the new formulation, the FDA approved Rinvoq/Rinvoq LQ for the:
 - Treatment of adults and pediatric patients 2 years of age and older with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers. Rinvoq was previously approved for PsA for adults only.
 - Treatment of patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis (pJIA) who have had an inadequate response or intolerance to one or more TNF blockers.
- Rinvoq is also approved for treatment of rheumatoid arthritis (RA), atopic dermatitis, ulcerative colitis, Crohn's disease, ankylosing spondylitis, and non-radiographic axial spondyloarthritis.
- The approval of Rinvoq/Rinvoq LQ for the expanded/new indications was supported by evidence from well-controlled studies of Rinvoq in adults with RA and PsA, pharmacokinetic data from adult patients with RA and PsA, and 51 pediatric patients with JIA with active polyarthritis, and safety data from 83 pediatric patients 2 to < 18 years of age with JIA with active polyarthritis.
- Rinvoq/Rinvoq LQ carries a boxed warning for serious infections, mortality, malignancy, major adverse cardiovascular events, and thrombosis.
- The recommended dose of Rinvoq for the treatment of pediatric patients with PsA and pJIA is based on body weight (see table below).

Patient weight	Rinvoq LQ	Rinvoq
10 kg to < 20 kg	3 mg (3 mL oral solution) twice daily	Not recommended
20 kg to < 30 kg	4 mg (4 mL oral solution) twice daily	Not recommended
≥ 30 kg	6 mg (6 mL oral solution) twice daily	15 mg (one tablet) once daily

- Rinvoq LQ oral solution is not substitutable with Rinvoq extended-release tablets. Changes between Rinvoq LQ oral solution and Rinvoq extended-release tablets should be made by the health care provider.
- Refer to the Rinvoq drug label for dosing for all its other indications.
- AbbVie's launch plans for Rinvoq LQ are pending. Rinvoq LQ will be available as a 1 mg/mL oral solution.