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Rinvoq access in India

How families in India source Rinvoq (upadacitinib) for nine FDA-approved immune-mediated indications through the CDSCO Rule 36 personal importation pathway.

Quick orientation

Rinvoq is AbbVie's oral small-molecule Janus kinase (JAK) inhibitor upadacitinib, engineered for JAK1 selectivity. The US FDA has approved it across nine indications: rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, atopic dermatitis in adults and adolescents, ulcerative colitis, Crohn's disease, polyarticular juvenile idiopathic arthritis, and giant cell arteritis. India families seek Rinvoq when CDSCO has no clear domestic approval and access is import-route dependent, or when the local payer landscape does not fund the JAK inhibitor for the patient's specific indication. The legal route is the Central Drugs Standard Control Organization (CDSCO) personal importation framework under Rule 36 of the Drugs and Cosmetics Rules 1945, using Form 12A application and Form 12B permit. Reserve Meds coordinates US-side sourcing, the documentation kit including boxed warning disclosure, room-temperature international logistics, and a single named coordinator for the case.

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Why patients in India need Rinvoq via NPP

India's CDSCO does not have a clear domestic approval for Rinvoq at this time; access is import-route dependent. That places Rinvoq in the third structural access-gap pattern the country module describes: not registered locally at all, even though the molecule is FDA-approved across nine indications and EMA-authorized across substantially the same set. India has a strong domestic biosimilar industry for biologics including adalimumab (Exemptia from Zydus Cadila, Adfrar from Torrent) and ustekinumab, but Rinvoq is a small-molecule oral tablet rather than a biologic, and no Indian generic of upadacitinib is available; the only legal route to the molecule is the originator AbbVie product through Rule 36 personal importation.

The drug module documents three patterns driving Rinvoq into the NPP queue. First, indication mismatch: even where some specialty distribution exists, local availability typically lags the full FDA label by several indications, leaving patients with psoriatic arthritis, axial spondyloarthritis, IBD, or giant cell arteritis without a locally registered route. Second, payer coverage: private insurance classifies JAK inhibitors as high-cost biologic-tier therapy with restrictive prior-authorization criteria. Third, oral biologic equivalent: patients who have failed or cannot tolerate self-injected TNF inhibitors or interleukin blockers value the once-daily oral route, and for the Gulf and India cash-pay archetype an oral immunomodulator with broad indication coverage is a defensible clinical choice when the locally registered route is closed.

The CDSCO Rule 36 personal importation pathway for Rinvoq

The legal foundation for personal import of a small quantity of medicine into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits import of small quantities of a drug, whose import would otherwise be prohibited under Section 10 of the Drugs and Cosmetics Act 1940, for the exclusive personal use of a named patient.

The mechanism is documented and accessible. Form 12A is the application for a permit to import a small quantity of a drug for personal use under the second proviso to Rule 36. Form 12B is the permit itself, issued by the office of the Drugs Controller General of India (DCGI) at FDA Bhawan, Kotla Road, New Delhi, or by a designated CDSCO Port Office. The application is accompanied by a prescription from a Registered Medical Practitioner (RMP) showing the RMP's National Medical Commission (NMC) registration number and the quantity required for treatment. The quantity of any single drug imported shall not exceed one hundred average doses per application, and Rinvoq's once-daily oral dosing fits comfortably within that envelope for a typical three-month supply.

CDSCO's published guidance states the Form 12B permit is issued on a priority basis, typically within one to two days for routine applications where the documentation is complete. In practice, families and hospitals plan for a two to four week window from physician decision to dispensed medicine, because the bulk of the elapsed time is upstream documentation assembly and downstream international logistics rather than the regulator's stamp.

For Rinvoq specifically, the clinical justification letter centers on five angles. First, the documented FDA-approved indication being prescribed, drawn from the nine-indication label. Second, prior therapy and response history, particularly inadequate response or intolerance to conventional DMARDs and to at least one biologic agent in most autoimmune indications, since the local payer logic for JAK inhibitor use sits at this step in the algorithm. Third, baseline workup per the FDA label: tuberculosis screening (interferon-gamma release assay or tuberculin skin test) given India's TB burden, hepatitis B and C screening, baseline complete blood count with lymphocyte and neutrophil and hemoglobin levels, baseline liver function tests, and baseline lipid panel. Fourth, the dosing plan with the specific tablet strength (15 mg once daily for most indications, 30 mg once daily for atopic dermatitis if inadequate response at 15 mg, 45 mg once daily for the 8-week UC induction or 12-week Crohn's induction, or weight-based oral solution for pediatric JIA), and any dose adjustments for renal or hepatic impairment or strong CYP3A4 modulators. Fifth, the boxed warning disclosure: the JAK class boxed warning covers serious infections, malignancy, major adverse cardiovascular events, thrombosis, and mortality, and the prescriber's documentation acknowledges patient counseling on this profile.

Where Rinvoq gets dispensed in India

India's tertiary specialty hospital network handles named-patient oral immunomodulator imports as established workflow. Institutions with established import pharmacy desks include the All India Institute of Medical Sciences (AIIMS) in New Delhi (apex public-sector institution and Centre of Excellence under the National Policy for Rare Diseases), Apollo Hospitals (Chennai flagship, plus Delhi, Bangalore, Hyderabad, Kolkata), Fortis Memorial Research Institute in Gurgaon and the broader Fortis network, Medanta in Gurgaon, Kokilaben Dhirubhai Ambani Hospital in Mumbai, MGM Healthcare in Chennai, Christian Medical College (CMC) in Vellore, and Manipal Hospitals in Bangalore.

For Rinvoq, the relevant clinical departments are rheumatology for RA, PsA, AS, nr-axSpA, JIA, and giant cell arteritis; dermatology for atopic dermatitis; and gastroenterology for Crohn's disease and ulcerative colitis. Rinvoq is a small-molecule oral tablet stable at controlled room temperature (20 to 25 degrees Celsius, with excursions permitted 15 to 30 degrees), so it does not require cold-chain infrastructure. That simplifies the dispensing point: any hospital outpatient pharmacy or licensed importer pharmacy can receive, store, and dispense the product under standard drug-licence conditions, and direct-to-patient delivery is not the model since dispensing remains within the licensed chain. If the treating specialist is at a smaller institution without an

import pharmacy desk, the practical route is to work with one of the centres above or with a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore that handles the filing and chain-of-custody documentation.

Real cost picture for Rinvoq in India

US wholesale acquisition cost for Rinvoq was approximately USD 7,090 for a 30-day supply as of early 2026, translating to an annual list-price reference near USD 85,000 per patient year on continuous daily dosing. Cash retail pricing at US pharmacies typically falls between USD 6,500 and USD 9,640 per month before insurance or coupon adjustment. International logistics for room-temperature oral tablet shipment to India typically adds USD 200 to USD 500 per consignment depending on lane and customs documentation, materially less than the cold-chain biologics line. Regulatory documentation handling, Indian customs handling at the destination airport, and the Reserve Meds concierge fee are separate transparent line items.

India invoices land in INR with the rupee floating against the dollar; in May 2026 USD/INR is in the 94 to 95 range. GST on most life-saving medicines is 5%; the specific HSN code and any customs duty position are confirmed at the documentation stage. None of Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa reimburse a Rule 36 personal import as a standard line item; the default posture is cash-pay, with documentation structured so the family can pursue reimbursement after the fact if the plan allows.

Typical timeline for Rinvoq in India

For Rinvoq, total elapsed time from the prescribing specialist's decision to the dispensed tablets typically runs two to three weeks, slightly shorter than the cold-chain biologic baseline because room-temperature shipment avoids the validated packout and lane discipline. The Form 12B permit issues in one to two days on routine documentation per CDSCO's published priority track. The bulk of the timeline is documentation assembly with the treating specialist (TB screen, hepatitis B and C screen, CBC, LFTs, lipid panel, indication justification, prior therapy summary, dosing plan including induction strength for UC or Crohn's), US-side sourcing alignment with AbbVie's specialty channel through McKesson and peers (where Rinvoq is broadly stocked with reliable lead times), international shipment, customs review of the Form 12B permit at the port of entry, and dispensing pharmacy receipt under its drug licence. The principal risk vector is customs documentation rejection or pre-authorization timeline at the destination authority, not US supply-side availability.

What your physician needs to provide

The treating Registered Medical Practitioner in India with a valid NMC registration number assembles the clinical package that travels with the Form 12A application. For Rinvoq that package includes: the patient's diagnosis and the FDA-approved indication being prescribed from the nine-indication label; severity assessment appropriate to the indication (DAS28 for RA, joint count and CRP for PsA, BASDAI for AS, EASI or IGA for atopic dermatitis, Mayo or CDAI for IBD, vasculitis activity for giant cell arteritis); the documented tuberculosis screen result and treatment of latent TB before initiation if positive, given India's TB burden; hepatitis B and C screening; baseline CBC with lymphocyte, neutrophil, and hemoglobin counts; baseline liver function tests; baseline lipid panel with the documented plan for reassessment at 12 weeks; prior therapy and response history showing inadequate response or intolerance to conventional DMARDs or to at least one biologic agent in the algorithm; the dosing plan with specific tablet strength and any dose adjustment for renal impairment, hepatic impairment, or strong CYP3A4

inhibitors or inducers per the FDA label; the documented boxed warning disclosure covering serious infection (including TB reactivation, invasive fungal infection, and opportunistic pathogens), malignancy, major adverse cardiovascular events, thrombosis, and mortality; and the prescription with NMC registration number. The Reserve Meds documentation kit references each of these elements so the package does not loop back through CDSCO for missing data.

Common questions about Rinvoq in India

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover Rinvoq imported under Rule 36?

Each plan handles named-patient imports case by case. None of the major private insurers reimburse a Rule 36 personal import as a standard line item, and where the drug is not on the standard formulary the case becomes harder rather than easier. Cash-pay is the default posture; Reserve Meds provides the documentation so the family can pursue reimbursement after the fact if the plan allows.

Will my CGHS or ESIC entitlement cover this?

CGHS provides for life-saving medicines not in the standard formulary to be considered by an Expert Committee under Special DG (DGHS), case by case. Drugs not approved by DCGI for use in India face a stricter Expert Committee review, and Rinvoq sits in that stricter bucket. ESIC's formulary is narrower. Neither scheme is structured for routine personal-import reimbursement of a JAK inhibitor; check eligibility before assuming coverage.

Can a private rheumatology, dermatology, or gastroenterology specialist sign the prescription?

Yes. Any Registered Medical Practitioner with a valid NMC registration number can support a Form 12A application. Specialists at AIIMS, Apollo, Fortis, Medanta, Kokilaben, MGM, CMC Vellore, and Manipal sign these letters routinely as part of institutional workflow.

What is the safety profile and what does the boxed warning say?

Rinvoq carries a boxed warning that applies to the JAK inhibitor class following the ORAL Surveillance cardiovascular safety study with tofacitinib. The boxed warning covers serious infections (including tuberculosis reactivation, invasive fungal infection, and opportunistic pathogens), malignancy (including lymphoma and non-melanoma skin cancer), major adverse cardiovascular events (MACE) including myocardial infarction and stroke, thrombosis (DVT, PE, arterial thrombosis), and mortality. The boxed warning is mandatory disclosure in any clinical conversation about Rinvoq.

What is the monitoring requirement?

Before initiation: TB screening, hepatitis B and C screening, baseline CBC with lymphocyte and neutrophil and hemoglobin levels, baseline LFTs, and baseline lipid panel. During therapy: periodic CBC, periodic LFTs, lipid reassessment at 12 weeks and as clinically indicated, and ongoing MACE risk-factor review. Adverse event reporting in India runs through the Pharmacovigilance Programme of India (PvPI) coordinated by the Indian Pharmacopoeia Commission; the reporting obligation stays with the prescribing physician.

How does Rinvoq compare to adalimumab biosimilars available in India?

The SELECT-COMPARE trial compared upadacitinib 15 mg once daily against adalimumab 40 mg every other week in methotrexate-inadequate-responder RA, with upadacitinib showing superior ACR50 response at week 12 and superior disease activity reduction at follow-up windows. India has multiple adalimumab biosimilars including Exemptia (Zydus Cadila) and Adfrar (Torrent) that are widely used and substantially cheaper than imported Rinvoq. The choice between an oral JAK

inhibitor and an injectable TNF biosimilar reflects clinician judgment on route preference, comorbidity, prior therapy, and MACE risk-factor profile; Reserve Meds coordinates the drug the specialist has named and does not direct substitution.

Where Reserve Meds fits in Rinvoq cases

Reserve Meds is a US-based concierge coordinator. We do not replace the treating specialist, we do not replace CDSCO, and we do not replace the hospital pharmacy or licensed importer. For Rinvoq cases destined for India, we orchestrate US-side sourcing of the originator AbbVie product in the specific tablet strength prescribed (15 mg, 30 mg, 45 mg, or pediatric oral solution), the documentation kit the physician needs to file under Rule 36 including boxed warning disclosure, room-temperature international logistics with standard documentation through customs handoff at Delhi, Mumbai, Bangalore, Chennai, or Hyderabad, and a single named coordinator who carries the case from first contact through dispensed medicine and into the reporting period. The procurement profile is favorable, with reliable US wholesaler availability through McKesson, Cardinal, and AmerisourceBergen; the principal variable is destination authority workflow, which is exactly what the documentation kit addresses.

Next step

If you are a family member, a treating physician, or a hospital pharmacy considering Rinvoq for an India case under Rule 36, the request route is a short intake on the Reserve Meds portal. We respond within 24 to 48 hours with eligibility and the documentation kit for your specialist.

Reserved for you.

About Rinvoq

Manufacturer: AbbVie

Modality: JAK1 inhibitor, oral tablet (room temperature)

Indications: 9 immune-mediated diseases including RA, PsA, AS, AD, UC, Crohn's, GCA

Full drug page ->

About India

Authority: CDSCO / DCGI

Pathway: Rule 36 / Form 12A, Form 12B

Tier 1 specialty hospital network

Full country page ->

See also

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[Humira in India](#)

[Skyrizi in India](#)

[Access pathways](#)