

[Skip to main content](#)

[Home](#) / [Drugs](#) / [Humira](#) / [In India](#)

Humira access in India

How families in India source reference Humira (adalimumab) through the CDSCO Rule 36 personal importation pathway alongside an extensive local biosimilar landscape that includes Exemptia and Adfrar.

Quick orientation

Humira is AbbVie's biologic adalimumab, the first fully human IgG1 monoclonal antibody approved by the FDA and a TNF-alpha inhibitor at the center of multiple immune-mediated disease algorithms. The US FDA has approved it across rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease in adults and pediatric patients 6 years and older, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa, polyarticular juvenile idiopathic arthritis from age 2, and non-infectious uveitis. India has a strong domestic biosimilar industry for adalimumab, with Exemptia (Zydus Cadila) and Adfrar (Torrent) being two of the most widely used Indian biosimilars, alongside several others. The cross-border named-patient pathway is therefore reserved for families specifically requesting reference Humira from AbbVie or a specific FDA-approved US biosimilar rather than a domestically registered Indian biosimilar. 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, validated cold-chain logistics, and a single named coordinator for the case.

Reserved for you.

Why patients in India need Humira via NPP

Adalimumab is one of the most broadly registered biologics in India. CDSCO has approved adalimumab and Indian biosimilars are widely available and substantially cheaper than imported reference Humira. The country module describes the three structural access-gap patterns; for reference Humira specifically in India, the gap is primarily the first pattern (registered but not stocked in the specific brand or SKU the prescription names) and the third pattern (the specific FDA-approved US biosimilar the family wants is not on the Indian market).

The drug module documents three patient-side patterns that drive NPP inquiry for Humira specifically. First, local supply gaps during shortage windows: when a local agent's stock of reference Humira runs short, or a specific SKU (pen versus syringe, citrate-free 100 mg/mL versus older citrate-containing 50 mg/mL) is temporarily unavailable, patients on continuous therapy cannot interrupt dosing without disease flare risk, and the cross-border named-patient route bridges the gap. Second, biosimilar substitution that the patient or treating physician declines: in some India cases, the prescriber documents a clinical rationale for non-substitution (for example, a patient stabilized on the originator who is not a candidate for switch under the specialist's reasoning), and the family pursues reference Humira through Rule 36. Third, cash-pay preference for product choice: affluent self-pay families who want reference Humira specifically, or a specific FDA-approved US biosimilar not registered in India, use the NPP pathway as the legal mechanism to obtain it. The first-line economic case for an Indian-domiciled patient generally favors a locally available biosimilar such as Exemptia or Adfrar; Reserve Meds

operates in the narrower segment where the prescription has specifically named the originator or a particular US-registered product.

The CDSCO Rule 36 personal importation pathway for Humira

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; for adalimumab dosed every other week, that envelope covers nearly four years of maintenance therapy in a single permit, although in practice shipments are sized to a 6 to 12 month supply to keep cold-chain exposure and inventory simple.

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 Humira specifically, the clinical justification letter centers on five angles. First, the documented FDA-approved indication being prescribed from the broad label. Second, the brand-specific rationale: where the patient is requesting reference Humira specifically (versus an available Indian biosimilar such as Exemptia or Adfrar), the prior treatment history and the specialist's non-substitution reasoning are documented. Third, tuberculosis screening, which is required before initiation per the FDA label and especially salient in India given the high TB burden, alongside hepatitis B virus screening. Fourth, the dosing plan with the specific presentation (40 mg pen or syringe, citrate-free 100 mg/mL formulation versus older citrate-containing 50 mg/mL, induction dosing for IBD or hidradenitis suppurativa where applicable, weight-based pediatric dosing for Crohn's 6 to 17 kg to less than 40 kg or polyarticular JIA from age 2). Fifth, where the patient is pediatric with IBD on concomitant azathioprine or 6-mercaptopurine, the hepatosplenic T-cell lymphoma (HSTCL) warning the FDA boxed warning calls out is acknowledged in the clinical letter. A complete CDSCO application also includes the treating physician's NMC registration number, the patient identifier and supporting records, product details, the dispensing facility's drug licence, and a chain-of-custody plan that preserves the 2 to 8 degrees Celsius envelope from the US source to the Indian dispensing pharmacy or patient address. The 14-day room-temperature excursion allowance gives meaningful operational flexibility for cross-border shipments to India provided the shipment lane is reliably under that window.

Where Humira gets dispensed in India

India's tertiary specialty hospital network handles named-patient cold-chain biologics as established workflow, and adalimumab subcutaneous self-injection makes the dispensing path

simpler than IV-induction products. Institutions with established import pharmacy desks include the All India Institute of Medical Sciences (AIIMS) in New Delhi, 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 Humira, the relevant clinical departments are rheumatology for RA, PsA, AS, and JIA; dermatology for plaque psoriasis and hidradenitis suppurativa; gastroenterology for Crohn's disease and ulcerative colitis; and ophthalmology for non-infectious uveitis. The product is dispensed under the hospital pharmacy or licensed importer's drug licence and is provided to the patient in cold-chain integrity with home-refrigeration instructions. 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 Humira in India

Reference Humira's US wholesale acquisition cost sits at roughly USD 6,900 per monthly supply (40 mg every-other-week dosing equates to two 40 mg doses per month). On an annualized basis this is approximately USD 80,000 to USD 90,000 per year for the most common adult RA, psoriasis, or AS dosing regimen at pre-biosimilar reference pricing. US biosimilar WACs vary widely (Hadlima launched at roughly 85% below reference Humira WAC; Amjevita launched with a dual-WAC strategy; Cyltezo and others priced at modest 5 to 7 percent discounts to retain rebate-driven formulary access). For India families specifically importing reference Humira or a specific US biosimilar under Rule 36, the cost stack is the US-channel acquisition cost plus international logistics, regulatory documentation handling, customs handling, and the Reserve Meds concierge fee, each transparently itemised.

The Indian biosimilar comparison is material. Exemptia and Adfrar list prices in India are dramatically lower than imported reference Humira; for cost-sensitive families, the locally registered biosimilar is the practical choice and the cross-border Rule 36 path does not improve the economics. The Rule 36 route makes sense only where the prescription has specifically named the originator or a specific US biosimilar that the family is willing to pay the premium for. India invoices land in INR with the rupee floating against the dollar; in May 2026 USD/INR is in the 94 to 95 range. India's Union Budget 2026-27 expanded customs duty exemptions on life-saving medicines and GST on most life-saving medicines is 5%; the specific HSN code and any customs 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, and where an Indian biosimilar is on formulary, plans are unlikely to pay the originator premium absent documented clinical rationale.

Typical timeline for Humira in India

For Humira, total elapsed time from the prescribing specialist's decision to the dispensed pen or syringe typically runs two to four weeks. 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 screen, indication justification, brand-specific rationale where the patient is requesting originator over Indian biosimilar, prior therapy summary, dosing plan), US-side sourcing alignment with AbbVie's specialty pharmacy channel through CVS Specialty, Accredo, Optum, or Walgreens Specialty,

validated cold-chain packout with continuous temperature loggers, international shipment, customs review of the Form 12B permit and cold-chain logger records at the port of entry, and dispensing pharmacy receipt under its drug licence. Cold-chain shipments add two to three days versus ambient on the international logistics leg, with the 14-day room-temperature excursion allowance providing operational flexibility for routes that stay within that window. PBM formulary moves in the US channel (Express Scripts removed reference Humira; Optum Rx narrowed preferred biosimilars to Amjevita in 2025) have thinned reference Humira availability at some US retail specialty channels, which can extend US-side sourcing time on certain SKUs and is flagged at intake.

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 Humira that package includes: the patient's diagnosis and the FDA-approved indication being prescribed; severity assessment appropriate to the indication; the brand-specific rationale where the patient is requesting reference Humira (or a specific US biosimilar) over an available Indian biosimilar such as Exemptia or Adfrar; the documented tuberculosis screen result and treatment of latent TB before initiation if positive, given India's TB burden; hepatitis B virus screening; ongoing vigilance plan for serious infection, malignancy, demyelinating disease, heart failure exacerbation, and lupus-like syndrome per the FDA label; the dosing plan with specific presentation (40 mg pen versus syringe, citrate-free 100 mg/mL versus older citrate-containing 50 mg/mL, induction sequence for Crohn's, UC, or hidradenitis suppurativa, weight-banded pediatric dosing for Crohn's 17 kg to less than 40 kg or polyarticular JIA from age 2); the patient-side education plan covering home refrigeration at 2 to 8 degrees Celsius in original carton, 14-day room-temperature excursion allowance up to 25 degrees, injection technique, sharps disposal, and not returning the product to refrigeration once room-temperature-stored; and the prescription with NMC registration number. For pediatric IBD cases on concomitant azathioprine or 6-mercaptopurine, the clinical letter notes the boxed-warning hepatosplenic T-cell lymphoma (HSTCL) risk documented in adolescents and young adults. 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 Humira in India

Why would I import reference Humira when Indian biosimilars like Exemptia and Adfrar are widely available?

The most common reasons families pursue reference Humira under Rule 36 rather than Exemptia, Adfrar, or another Indian biosimilar are continuity of the brand the patient was previously stabilized on (often on the originator while living in the US, EU, or Gulf), the treating specialist's documented non-substitution recommendation, or a clinical reason to source a specific FDA-approved US biosimilar not registered in India. For most cost-sensitive Indian-domiciled families, an Indian biosimilar is the practical choice and the Rule 36 import path does not improve the economics; Reserve Meds coordinates the specific product the prescription names without advocating for one over another.

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover reference Humira 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 an Indian biosimilar is

on formulary, plans are unlikely to pay the originator premium absent documented clinical rationale. Cash-pay is the default posture.

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 does the Humira boxed warning say?

Humira carries a Boxed Warning for serious infections (including tuberculosis, invasive fungal infections, and bacterial sepsis) and for malignancy, with specific post-marketing reports of hepatosplenic T-cell lymphoma (HSTCL) in adolescent and young adult patients with inflammatory bowel disease, most of whom received concomitant azathioprine or 6-mercaptopurine. TB screening before initiation is mandatory, and the patient's prescribing physician owns clinical risk evaluation throughout therapy.

What is the monitoring requirement?

Per the FDA label, baseline TB screening before therapy initiation, hepatitis B virus screening, and ongoing vigilance for serious infection, malignancy, demyelinating disease, heart failure exacerbation, and lupus-like syndrome. Periodic CBC and clinical follow-up are standard. 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. Reserve Meds does not provide clinical monitoring; the patient's prescriber and local clinical care team retain that responsibility.

How does Humira compare to alternatives?

Within the TNF-alpha inhibitor class, prescribers consider infliximab (Remicade and biosimilars), etanercept (Enbrel), certolizumab pegol (Cimzia), and golimumab (Simponi). For specific indications, non-TNF biologics (ustekinumab including Stelara and Indian biosimilars, vedolizumab, risankizumab Skyrizi, secukinumab, ixekizumab, upadacitinib Rinvoq, tofacitinib) are alternatives. Class selection is a clinical decision made by the treating physician; Reserve Meds coordinates the drug the specialist has named.

Where Reserve Meds fits in Humira 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 Humira cases destined for India, we orchestrate US-side sourcing of the originator AbbVie product (or a specific FDA-approved US biosimilar where prescribed) matching the specific presentation called for (40 mg pen versus syringe, citrate-free 100 mg/mL versus older citrate-containing 50 mg/mL, weight-banded pediatric dosing), the documentation kit the physician needs to file under Rule 36 including the brand-specific rationale where the prescription specifies originator over Indian biosimilar, validated cold-chain international logistics with continuous temperature monitoring 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. Cold-chain qualification of the destination lane is the single highest operational risk and is verified before any shipment commits, with the 14-day room-temperature excursion allowance providing flexibility for routes that stay within that window.

Next step

If you are a family member, a treating physician, or a hospital pharmacy considering reference Humira or a specific US biosimilar 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 Humira

Manufacturer: AbbVie

Modality: TNF-alpha inhibitor, cold-chain biologic (2-8 C, 14-day RT excursion allowed)

Indications: RA, PsA, AS, Crohn's (adult and pediatric 6+), UC, plaque psoriasis, HS, JIA (2+), uveitis

Full drug page ->

About India

Authority: CDSCO / DCGI

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

Extensive local biosimilar landscape: Exemptia (Zydus Cadila), Adfrar (Torrent), others

Full country page ->

See also

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[Stelara in India](#)

[Rinvoq in India](#)

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[Access pathways](#)