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## Humira access in Saudi Arabia: the SFDA Personal Importation Program

How KSA patients legally obtain reference Humira (adalimumab) when a specific brand or presentation matters amid a crowded global biosimilar landscape and shifting local stocking.

*Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team.*

### Quick orientation

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Humira (adalimumab) is the original fully human anti-TNF monoclonal antibody, manufactured by AbbVie, approved by the US FDA in December 2002 for rheumatoid arthritis and since extended to psoriatic arthritis, ankylosing spondylitis, Crohn's disease (adult and pediatric 6 and older), ulcerative colitis, plaque psoriasis, hidradenitis suppurativa, polyarticular juvenile idiopathic arthritis, and non-infectious uveitis. The Saudi Food and Drug Authority (SFDA) has registered Humira through AbbVie's regional affiliate, and adalimumab is one of the most broadly available biologics across the Kingdom. The KSA-specific story in 2026 is the biosimilar landscape: more than ten FDA-approved adalimumab biosimilars (Amjevita, Abrilada, Cyltezo, Hadlima, Hyrimoz, Yusimry, Hulio, Simlandi, others) have launched in the US, several with FDA interchangeability designation, and PBM formulary moves have accelerated displacement of the reference product. KSA hospital and insurer formularies follow the global pattern with local biosimilar stocking and uneven reference-product availability. KSA patients use the SFDA Personal Importation Program for Humira during local supply gaps, where the prescribing physician has documented non-substitution to biosimilar, or where the specific citrate-free 100 mg/mL or weight-banded pediatric SKU is not in local stock.

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### Why KSA patients need Humira through the named-patient pathway

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Given that Humira is broadly registered across the Gulf and India, NPP demand for cross-border Humira is narrower than for unregistered drugs. The patient inquiries that reach Reserve Meds fall into three recognizable patterns specific to the Saudi market.

First, local supply gaps during shortage windows. When a local agent's stock of a specific SKU (pen versus syringe, 40 mg versus 80 mg, citrate-free 100 mg/mL versus older citrate-containing 50 mg/mL) runs short, patients on continuous therapy cannot interrupt dosing without disease flare risk. Cross-border named-patient supply bridges the gap during the local restocking interval.

Second, biosimilar substitution that the patient or treating physician declines. KSA payer formularies and public-sector procurement, including under the Health Sector Transformation Program, increasingly default to a specific locally registered biosimilar. Patients who have stabilized on reference Humira (or on a different biosimilar) and whose treating physician documents a clinical rationale for non-substitution may pursue cross-border supply of the specific product the prescribing physician has named. This pattern is most common in long-standing IBD

and rheumatoid arthritis patients whose disease was stabilized on a specific product over many years.

Third, cash-pay preference for product choice. Affluent self-pay patients in Riyadh, Jeddah, and the Eastern Province who want a specific named product (reference Humira specifically, or a specific FDA-approved US biosimilar not registered locally) use the SFDA PIP as the legal mechanism. The patient pays cash; Reserve Meds coordinates the regulatory filing, the cold-chain logistics, and the prescriber documentation.

In all three patterns, the SFDA PIP is the lawful mechanism, and the prescriber's documented clinical rationale governs.

## **The SFDA Personal Importation Program for Humira**

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The Personal Importation Program allows an SCFHS-licensed physician to request import of a specific medicine for a specific named patient when the medicine is approved by a recognized reference authority (US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and a clinically equivalent locally registered alternative is not suitable for the patient. For Humira, the "clinically equivalent locally registered alternative" frame typically requires the physician to document why a locally stocked biosimilar is not suitable in this specific case, rather than arguing that adalimumab generally is unavailable.

A complete application includes a clinical justification letter from the treating physician (diagnosis with ICD-10 coding, severity, prior therapies attempted with outcomes, why the locally stocked biosimilar is not suitable, the specific drug, brand, presentation, dose, and duration requested), SCFHS registration verification in the relevant specialty (rheumatology, gastroenterology, dermatology, pediatrics, ophthalmology, or appropriate specialty), an anonymized patient identifier linked to the hospital record, full product details (brand name Humira, generic name adalimumab, manufacturer AbbVie, country of origin, strength, dosage form citrate-free 100 mg/mL or citrate-containing 50 mg/mL where relevant, pack size, requested quantity, lot, and expiry), the destination dispensing facility license, and a chain-of-custody plan from the US release point through international transit with cold-chain validation to the receiving Saudi pharmacy.

For Humira specifically, three elements drive the clinical-justification angle. First, brand and SKU specification. The clinical letter explicitly names reference Humira (AbbVie) and the exact SKU (Humira Pen versus prefilled syringe, citrate-free 100 mg/mL versus citrate-containing 50 mg/mL, pediatric 20 mg versus adult 40 mg or 80 mg) because a generic adalimumab prescription may default to whatever the local agent stocks. Second, the FDA boxed warning. The Humira label carries warnings for serious infections including tuberculosis (including reactivation of latent TB), invasive fungal infections, bacterial sepsis, and malignancy. There is also a specific post-marketing concern for hepatosplenic T-cell lymphoma (HSTCL) in adolescent and young adult patients with inflammatory bowel disease, most of whom received concomitant azathioprine or 6-mercaptopurine. The clinical justification letter documents TB screening (IGRA or PPD), hepatitis B serology, and patient counseling on these risks. Third, prior-line and non-substitution documentation, where the prescriber has determined that biosimilar substitution is not clinically appropriate for this individual patient.

Approval timelines for routine cases run 10 to 21 business days. Complex cases (pediatric IBD with HSTCL counseling, brand non-substitution arguments, less-common SKUs) can extend to 6 to 10 weeks.

## Where Humira gets dispensed in Saudi Arabia

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For SC self-administration after appropriate prescriber-supervised training, any SFDA-licensed hospital outpatient pharmacy or specialty importer with 2 to 8 degrees Celsius cold-chain storage and continuous monitoring qualifies as the dispensing facility. The institutions that handle named-patient imports as established workflow include King Faisal Specialist Hospital and Research Centre (KFSH&RC) in Riyadh, Jeddah, and Madinah; King Abdulaziz Medical City (KAMC) and the Ministry of National Guard Health Affairs network (MNGHA); King Saud University Medical City (KSUMC); Dr. Sulaiman Al Habib Medical Group (HMG) across Riyadh, Jeddah, and the Eastern Province; Saudi German Health hospitals; Dr. Soliman Fakeeh Hospital in Jeddah; and Dallah Hospital in Riyadh. All of these centers have established rheumatology, gastroenterology, dermatology, and pediatric subspecialty programs that handle TNF inhibitor maintenance therapy as routine workflow.

For physicians at smaller hospitals without internal import infrastructure, the practical pattern is to route the case through an SFDA-licensed specialty importer in Riyadh or Jeddah that files the PIP application and dispenses through the prescribing institution's pharmacy. Patient-side home refrigeration confirmation is part of the patient onboarding kit; the cold-chain handoff ends at the dispensing pharmacy and the patient stores the pen or syringe in the original carton at 2 to 8 degrees Celsius until use.

## Real cost picture for Humira in Saudi Arabia

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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. At the SAR peg of approximately 3.75 to the dollar, this translates to roughly SAR 25,900 per month and SAR 300,000 to SAR 338,000 annualized at US WAC equivalents.

Biosimilar WACs vary widely. Hadlima launched at roughly 85 percent below reference Humira WAC. Amjevita launched with a dual-WAC strategy (one 55 percent below, one 5 percent below). Cyltezo and several others priced at modest 5 to 7 percent discounts to retain rebate-driven formulary access. International payer pricing is country-specific and generally well below US WAC; published EU and MENA tender prices typically run 30 to 60 percent below US WAC for the reference product. The KSA price differential between reference Humira and the locally stocked biosimilar is part of the conversation the prescriber has with the patient about non-substitution.

International logistics for cold-chain biologic shipment into Riyadh or Jeddah typically runs USD 400 to USD 1,500 (approximately SAR 1,500 to SAR 5,600) per shipment. The 14-day room-temperature excursion runway on the Humira label gives meaningful operational flexibility for the Gulf shipping lane provided the cold chain is broken only at the dispensing pharmacy. Reserve Meds' concierge fee is itemised separately on every firm quote. The myAbbVie Assist income-eligible patient assistance program and the Humira Complete copay assistance, nurse ambassadors, and injection training are US-only programs and do not extend internationally.

## Typical timeline for Humira in Saudi Arabia

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SFDA routine processing is typically 10 to 21 business days from a complete filing. Cold-chain shipment adds 2 to 3 days versus ambient because validated thermal packaging and continuous

temperature logging are mandatory. The 14-day room-temperature excursion runway on the FDA label is a meaningful operational advantage for shipments into the Gulf because customs clearance windows are not as time-pressured as for shorter-excursion biologics. End-to-end, most adult RA, psoriasis, or AS cases complete within 4 to 7 weeks from first complete documentation. Pediatric IBD cases with weight-banded dosing and the HSTCL counseling workflow may run 5 to 8 weeks. Reorders for ongoing chronic therapy typically move faster than the first cycle once the local institutional relationship is in place.

## What your physician needs to provide

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For an SCFHS-licensed rheumatologist, gastroenterologist, dermatologist, pediatric specialist, or ophthalmologist prescribing Humira through the PIP pathway, the clinical justification letter documents diagnosis with ICD-10 coding, severity scoring, prior therapy history with outcomes (methotrexate, conventional DMARDs, prior biologics or biosimilars tried), and the clinical rationale for the specific reference Humira (or specific FDA-approved biosimilar SKU) being prescribed.

The letter specifies the exact dosing plan per the FDA-approved label. Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis: 40 mg SC every other week, with dose escalation considered for some adult RA patients not taking methotrexate. Crohn's disease (adult): induction 160 mg on Day 1, 80 mg on Day 15, then maintenance 40 mg every other week starting Day 29. Crohn's disease (pediatric 6 and older): weight-based induction with 160 mg Day 1, 80 mg Day 15, then 40 mg every other week for patients 40 kg and above; reduced doses for 17 kg to less than 40 kg. Ulcerative colitis (adult): 160 mg Day 1, 80 mg Day 15, then 40 mg every other week. Plaque psoriasis: 80 mg loading dose, then 40 mg every other week one week later. Hidradenitis suppurativa: 160 mg Day 1, 80 mg Day 15, then 40 mg every week. Polyarticular JIA (2 years and older): weight-based 20 mg or 40 mg every other week. Non-infectious uveitis: 80 mg loading dose, then 40 mg every other week one week later.

The monitoring plan documents baseline tuberculosis screening (IGRA or PPD), 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. For pediatric IBD patients, the HSTCL discussion is explicitly documented, particularly where concomitant azathioprine or 6-mercaptopurine is being used. The treating physician's SCFHS registration, the dispensing facility license number, and the pharmacy in charge of dispensing complete the package.

## Common questions about Humira in Saudi Arabia

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**The biosimilars are cheaper and locally stocked. Why pursue reference Humira?** The decision is your specialist's. Common documented rationales include long-term stabilization on reference Humira where the prescriber judges non-substitution clinically appropriate, prior adverse experience with biosimilar switching, or a specific FDA-approved US biosimilar SKU (Amjevita, Abrilada, Cyltezo, Simlandi, others) not currently stocked locally that your specialist has named. Reserve Meds coordinates whichever specific product the prescription names.

**Will Bupa Arabia, Tawuniya, or MedGulf cover reference Humira?** Each plan handles biologic claims case by case. Many KSA plans favor the biosimilar tier on formulary; reference Humira may require additional prior authorization with a non-substitution clinical justification. We supply the documentation that allows the insurer to assess; the claim itself sits with you or your hospital.

**What is HSTCL and does it apply to my child?** Hepatosplenic T-cell lymphoma is a rare, aggressive, and almost always fatal lymphoma. Post-marketing reports have described cases in adolescent and young adult IBD patients receiving TNF inhibitor therapy including Humira, most of whom were also taking azathioprine or 6-mercaptopurine. Your pediatric gastroenterologist briefs you on this risk before initiating therapy. This warning is class-relevant for anti-TNF biologics.

**What about the 14-day room-temperature excursion?** The FDA label permits storage at room temperature up to 25 degrees Celsius for a single period of up to 14 days, with protection from light. Once removed from refrigeration to room temperature for that period, the product must not be returned to the refrigerator and must be discarded if not used within 14 days. This gives operational flexibility for travel and home handling but is not unlimited.

**Citrate-free 100 mg/mL or citrate-containing 50 mg/mL: does it matter?** AbbVie transitioned the bulk of US supply to the citrate-free 100 mg/mL formulation, which patients report as less painful at injection. Local KSA stocking may include either or both. The prescription should specify which formulation, and the PIP file matches the prescription.

**My physician is at HMG in Jeddah. Can they sign the PIP?** Yes. SCFHS-licensed specialists at HMG, KFSH&RC, KAMC, MNGHA, KSUMC, Saudi German, Fakeeh, Dallah, and other major centers have signing authority under their institutional license.

## **Where Reserve Meds fits in Humira cases**

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Reserve Meds is a US-based concierge coordinator. We do not replace your rheumatologist, gastroenterologist, dermatologist, pediatric specialist, or ophthalmologist, we do not replace SFDA, and we do not replace your dispensing pharmacy. For Humira specifically, we orchestrate US-side sourcing of reference Humira or the specific FDA-approved biosimilar SKU your prescriber has named, through a DSCSA-compliant specialty channel that distinguishes one product from another in every line of procurement, build the documentation packet your physician submits to the SFDA Personal Importation Program with explicit non-substitution language where the prescriber has so determined, coordinate validated cold-chain logistics with continuous temperature logging into Riyadh or Jeddah, and assign a single named coordinator through the chronic-therapy reorder cycle. No prior Reserve Meds case experience for Humira in KSA is logged yet; standard NPP coordination under our cold-chain biologic playbook applies, with patient-side home refrigeration confirmation and injection-training reference included in every onboarding kit.

## **Next step**

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If your Saudi specialist has prescribed Humira and you are weighing the cross-border route, the next step is a short waitlist request. We confirm eligibility within 24 to 48 hours and send a documentation kit to your physician.

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