

# Farxiga access in India

How Indian patients access Farxiga (dapagliflozin), the SGLT2 inhibitor with cardiovascular and renal protection benefits, when the originator brand is preferred over the widely available Indian generics.

*Last reviewed 2026-05-12 by Reserve Meds clinical & regulatory team. This page combines the India country regulatory module with the Farxiga drug module to describe the path Indian patients actually walk for the originator product.*

## Quick orientation

Farxiga (dapagliflozin) is a sodium-glucose cotransporter 2 (SGLT2) inhibitor first approved by the US Food and Drug Administration in January 2014 for type 2 diabetes, with subsequent approvals for heart failure with reduced ejection fraction, heart failure with preserved ejection fraction, and chronic kidney disease. The product is marketed approximately by AstraZeneca. Across the dapagliflozin label, the molecule has demonstrated reductions in cardiovascular death, heart failure hospitalisation, and progression of kidney disease in landmark trials. Reserved for you.

## Why this drug is hard to source in India (originator vs generic)

Unlike most pages in this catalogue, the access friction for Farxiga in India is not a registration gap. Dapagliflozin is widely available in India both as the originator AstraZeneca product (marketed in India under licensed branding) and as multiple Indian-manufactured generics that entered the market following expiry of dapagliflozin's compound patent in India and the resulting wave of generic launches. Indian generics of dapagliflozin sell at a small fraction of US originator pricing and meet Indian Pharmacopoeia standards under CDSCO oversight. For most Indian type 2 diabetes patients, a domestically manufactured dapagliflozin generic prescribed by their physician is the practical and economic choice.

The Reserve Meds access conversation for Farxiga in India is therefore narrower. It applies where a patient or treating physician has a specific clinical or quality reason to prefer the US originator product. Examples include international patients temporarily resident in India who have been stabilised on the US-supplied originator and prefer continuity, patients enrolled in a multinational clinical research program tied to the originator product, or patients whose physician judges that originator pharmacokinetic and excipient consistency

matters for their specific case. For everyone else, the Indian generic is the right answer and Reserve Meds does not have a role.

## **The CDSCO personal-import pathway under Rule 36**

Where the originator US product is the right answer for a specific patient, the legal foundation for import is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits import of a small quantity 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. Form 12A is the application; Form 12B is the permit issued by the office of the Drugs Controller General of India. The application is accompanied by a prescription from a Registered Medical Practitioner showing the practitioner's NMC registration number. Because dapagliflozin is already CDSCO-registered (in licensed Indian branding) and generic versions are available, the Form 12A justification specifically addresses why the named patient requires the originator US product rather than a locally available generic.

## **Real costs in INR and USD**

The US wholesale acquisition cost for Farxiga is approximately USD 600 to 700 per 30-day supply at the 10 mg dose, the standard adult dose across all approved indications. In INR at the prevailing 94 to 95 range, that translates to approximately INR 56,000 to 67,000 per month for the originator product imported from the US. By comparison, an Indian-manufactured dapagliflozin generic typically retails for approximately INR 200 to 400 per month at the 10 mg dose, depending on the brand and pack size. The cost differential is substantial and is the reason originator import is rarely the economically rational choice for a routine case. Where the originator is specifically indicated, Reserve Meds operates with full price transparency, and the patient or family makes an informed choice with the actual delta in view.

## **Timing, what to expect**

For an originator Farxiga import case, the timeline runs two to four weeks from physician decision to dispensed product. The Form 12B permit issues on the CDSCO documented one to two business day priority timeline. Documentation assembly takes three to five business days. US-side sourcing and shipment runs one to two weeks. For ongoing supply, Reserve Meds aligns refill cycles to a four to eight week reorder rhythm.

## **What your physician needs**

For an originator Farxiga import where Indian generics are available, the clinical justification letter documents the patient's diagnosis (type 2 diabetes, heart failure with

reduced or preserved ejection fraction, chronic kidney disease, or a combination), the specific reason originator product is required rather than an Indian generic, and the dosing plan. The treating physician's NMC registration number appears on the prescription. The dispensing facility's drug licence number is part of the submission package. Adverse event monitoring for SGLT2 inhibitors (genitourinary infections, volume depletion, diabetic ketoacidosis risk in select populations) is documented in the treating physician's monitoring schedule.

## **Customs clearance and IOR**

Customs at the port of entry reviews the Form 12B permit, the commercial documentation, and the importer's drug licence. The Importer of Record is the licensed dispensing facility or specialty importer holding the wholesale drug licence under the Drugs and Cosmetics Rules. Reserve Meds does not act as the IOR. Farxiga tablets ship ambient and do not require cold-chain handling, which simplifies the logistics chain versus most products in this catalogue.

## **Pharmacovigilance**

India operates the Pharmacovigilance Programme of India (PvPI) coordinated by the Indian Pharmacopoeia Commission. Treating physicians report adverse events through PvPI. For dapagliflozin, the post-marketing safety profile is well characterised across years of use; the prescribing physician's standard monitoring schedule covers the SGLT2 inhibitor class warnings.

## **Where Reserve Meds fits**

Reserve Meds is a US-based concierge coordinator. For Farxiga in India, our role is narrow. We orchestrate originator US product import only where a specific clinical or continuity reason justifies it. For routine Indian patients with type 2 diabetes, heart failure, or chronic kidney disease, we encourage the patient and their treating physician to use the locally available Indian generic dapagliflozin at a fraction of the cost.

## **Next step**

If there is a specific reason the originator Farxiga product is required for a patient in India, the waitlist is the first step. We respond within 24 to 48 hours with an eligibility confirmation, and we will be candid if the case is better served by the Indian generic.

*Reserved for you.*

## Related

- Farxiga clinical resource
- India country page
- CDSCO personal-import pathway

## Sources

1. FDA approval, Farxiga (dapagliflozin), AstraZeneca, NDA approval January 2014 for type 2 diabetes with subsequent expansions for heart failure and chronic kidney disease.
2. CDSCO, Procedure for Permission to Import Small Quantities of Drugs for Personal Use (Form 12A / Form 12B under Rule 36, Drugs and Cosmetics Rules 1945).
3. Indian Pharmacopoeia Commission, generic dapagliflozin quality standards under CDSCO oversight.

## Common questions Indian families ask

**Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover this?** Each Indian private insurer assesses named-patient imports case by case. None of the major private insurers reimburse a Rule 36 personal import as a standard line item. Some have reimbursed full or partial drug cost where the underlying medicine is on the formulary and the named-patient route operated as a stocking workaround. Reserve Meds supplies the documentation that lets your insurer evaluate. The claim itself is filed by the patient or the hospital. Cash-pay remains the default posture for Reserve Meds patient cases.

**Will my CGHS or ESIC entitlement cover this?** CGHS (Central Government Health Scheme) provides for life-saving and anti-cancer medicines not in the standard formulary to be considered case by case by an Expert Committee under the Special DG (DGHS) where the prescribing specialist documents the requirement. Drugs not approved by the DCGI for use in India face a stricter Expert Committee review. ESIC's formulary is narrower. Neither scheme is structured for routine personal-import reimbursement; check eligibility with your CGHS Wellness Centre or the ESIC dispensary before assuming coverage.

**Will my AIIMS, Tata Memorial, Apollo, Fortis, Medanta, Kokilaben, MGM, CMC Vellore, or Manipal physician's letter be sufficient?** Yes. A Registered Medical Practitioner with a valid National Medical Commission registration number can support a Form 12A application. Physicians at AIIMS, Tata Memorial Centre, government medical colleges, and state-run tertiary hospitals routinely do so. Private-sector specialists at Apollo, Fortis, Medanta, Kokilaben Dhirubhai Ambani Hospital, MGM Healthcare, CMC Vellore, and Manipal Hospitals also have signing authority subject to their institutional drug licence.

**What if my treating institution does not have an import pharmacy desk?** The practical route is to work with one of the named tertiary centres that handles compassionate and named-patient imports as established workflow, or with a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore that handles the documentation and chain-of-custody on behalf of smaller hospitals or independent specialists. Reserve Meds aligns with the importer named on the Form 12B permit.

**Can I receive the drug at home, or do I need a hospital?** The dispensing facility must hold a valid drug licence under the Drugs and Cosmetics Rules. For oral medicines, a hospital outpatient pharmacy or a licensed import pharmacy is the dispensing point. For infusion products, the medicine ships to the infusion centre where the patient will receive it. Direct-to-home delivery outside a licensed dispensing facility is not the model.

**What about pediatric patients?** The Rule 36 framework applies the same way for pediatric patients. The clinical justification letter typically includes weight-adjusted dosing and pediatric-specific monitoring. AIIMS, Tata Memorial, Apollo, Kokilaben, and CMC Vellore handle pediatric named-patient imports routinely. Where the indication is approved in adults only, the off-label use is the physician's clinical judgement and is documented as such in the Form 12A letter.

**Does FCRA affect a patient case?** The Foreign Contribution (Regulation) Act 2010 (FCRA), as proposed to be amended by the Foreign Contribution (Regulation) Amendment Bill 2026, regulates foreign donations to Indian organisations and individuals. For a patient family paying for the medicine themselves, FCRA is generally not engaged. Where a foreign foundation or diaspora group is funding a treatment, FCRA registration of the recipient organisation and the donation route can become relevant; the structure should be reviewed with counsel before funds move. Reserve Meds does not provide FCRA legal advice; we flag the question so it reaches the right adviser early.

**What is the role of the Indian Pharmacopoeia Commission?** The Indian Pharmacopoeia Commission coordinates the Pharmacovigilance Programme of India (PvPI) and publishes the Indian Pharmacopoeia, the legal compendium of pharmaceutical standards in India. For imported originator products under Rule 36, the PvPI reporting framework applies to adverse event surveillance, and the prescribing physician is the reporting party. The Indian Pharmacopoeia is the reference standard against which Indian-manufactured products are tested; imported originator products carry their reference-country pharmacopoeial standards (typically USP for FDA-approved products).

**How does this compare with access in the UAE or Saudi Arabia?** India's Rule 36 framework with the published Form 12B priority timeline (one to two business days for routine documentation) is often faster than the SFDA Personal Importation Program in Saudi Arabia (typically 10 to 21 business days routine) and broadly comparable to the UAE Emirates Drug Establishment pathway. India's offsetting friction is the customs and logistics layer rather

than the regulator's stamp. India's tertiary specialty hospital depth substantially exceeds any single peer country in the South Asia and GCC region, which usually offsets the longer end-to-end cycle for complex cases.

### **What documentation does my family need to assemble before contacting Reserve Meds?**

The minimum useful package is the treating physician's name and registration number, the patient's diagnosis and current treatment summary, recent relevant investigations (imaging, biopsy, molecular pathology, blood work as applicable), and a contact pathway to the dispensing facility you intend to use. With that package, Reserve Meds can complete eligibility within 24 to 48 hours and route the documentation kit to your physician.

## **How Indian families coordinate across cities and countries**

For Indian families, the coordination problem is often distributed across multiple cities and sometimes multiple countries. A grandmother in Hyderabad, an oncologist at Tata Memorial in Mumbai, an adult child in Bangalore managing logistics, and a son in Dubai or London paying the invoice is a common configuration. The Reserve Meds single named coordinator model is built for exactly this pattern. One coordinator carries the case file, one chain of correspondence captures the decisions and documents, and one set of contact records reaches every family member who needs visibility into the case, regardless of how many cities the family touches or how many time zones the case spans. The Reserve Meds patient portal at [portal.reservemed.com](http://portal.reservemed.com) holds the document set and the case timeline; the coordinator handles the email, phone, and WhatsApp follow-through that the case needs at each step.

For smaller cities where the local hospital does not maintain an import pharmacy desk, the practical route is to work with a CDSCO-licensed specialty importer in Mumbai, Delhi, Bangalore, Chennai, or Hyderabad. The importer carries the CDSCO relationship, the customs broker relationship, and the chain-of-custody documentation. Reserve Meds aligns with the importer on US-side sourcing and with the treating physician on clinical documentation. The patient sees one face throughout, which is the named coordinator.

## **The patient experience, step by step**

From the family side, the sequence looks like this. Your physician decides this drug is the right next step. That is a clinical decision and stays with them. Your physician or the hospital pharmacy team reaches out to Reserve Meds, or the patient submits a request through the Reserve Meds portal and Reserve Meds connects with the physician. Reserve Meds confirms eligibility within 24 to 48 hours and sends a documentation kit to your physician, including the Form 12A reference, the clinical justification letter template, and

the chain-of-custody plan. Your physician completes the documentation, attaches the prescription with their NMC registration number, and the application goes to CDSCO through the appropriate port office or the DCGI New Delhi office, or via the hospital's licensed importer. The Form 12B permit issues on the documented priority timeline. While the permit issues, Reserve Meds aligns US-side sourcing and the shipment plan with the dispensing pharmacy. The shipment moves cold-chain or ambient as appropriate. Customs at the destination port reviews the permit and clears the consignment. The dispensing pharmacy receives, logs, and stores the medicine according to its drug licence requirements. Your physician initiates therapy. Adverse event reporting through PvPI continues for the duration of therapy.

**Review and oversight.** Content on this page is reviewed by the Reserve Meds clinical and regulatory team. A US-licensed pharmacist reviews every prescription before dispensing. Regulatory posture is informational, not legal advice; case-specific questions route to retained outside counsel. [Review methodology >](#)

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