Xtandi access in India through the CDSCO Rule 36 Form 12A pathway

How Indian prostate cancer patients who want brand-sourced US Xtandi (enzalutamide) across the four FDA-approved disease states source the original product through Rule 36, with the indication-specific documentation Indian uro-oncologists need to file the Form 12A application.

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

Quick orientation

Xtandi is the brand name for enzalutamide, an oral androgen receptor pathway inhibitor (ARPI). The US FDA approved Xtandi initially on 31 August 2012 for metastatic castration-resistant prostate cancer (mCRPC) post-docetaxel, and the label has expanded across four prostate cancer disease states: mCRPC chemotherapy-naive (September 2014), non-metastatic CRPC (July 2018), metastatic castration-sensitive prostate cancer (mCSPC, December 2019), and non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis (16 November 2023). Xtandi is registered in India through local Astellas affiliates, and generic enzalutamide options are commercially available in the Indian market. Patients still reach for brand US-sourced Xtandi through Rule 36 for three specific reasons described below. Reserve Meds coordinates the US-side sourcing and the documentation kit your Indian uro-oncologist needs to file the Form 12A application for brand cash-pay access. Reserved for you.

Why Indian patients reach for brand US-sourced Xtandi through the named-patient pathway

Xtandi is registered in India and several Indian generics manufacturers produce enzalutamide. So why does the Rule 36 pathway matter here? The country module's framing applies across three Indian-specific patterns rather than a single missing-registration gap. First, indication lag. The newest FDA approval, nmCSPC with high-risk biochemical recurrence (November 2023), is not uniformly reflected in the Indian label yet. Patients whose Indian uro-oncologist wants Xtandi at this earlier disease state under the FDA-supported framework, and where the local label or local generic positioning still emphasises mCRPC or mCSPC, may legitimately route through Rule 36. Second, sourcing assurance. In a market where credible counterfeit risk in oncology supply chains is a documented concern, sophisticated cash-pay patients prefer US-sourced brand product through a documented DSCSA chain of custody over locally registered stock from less transparent supply lines. Third, formulary and reimbursement gaps. Even where Xtandi is locally registered, public-payer formularies in India may exclude or restrict it; private insurance denials drive NPP demand when the patient is cash-pay-capable and is unwilling to wait through a formulary appeal cycle.

The relevant comparator inside India is the locally available generic enzalutamide market. Reserve Meds is explicit on the framing: locally registered generic enzalutamide is a legitimate option that your uro-oncologist may recommend, and the brand-cash-pay Rule 36 route exists for the specific subset of patients and clinicians who have decided on brand US-sourced product for the reasons above. Reserve Meds does not promote brand over generic; we coordinate access for the patients who have made that choice with their physicians.

The CDSCO Rule 36 personal import pathway for Xtandi

The legal foundation for personal import of unregistered or brand-sourced medicines into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits import of small quantities of a drug 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

(DCGI) at FDA Bhawan, Kotla Road, New Delhi, or by designated CDSCO Port Offices. CDSCO 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.

For Xtandi specifically, the clinical-justification angle that anchors the Form 12A application is the multi-state prostate cancer indication framework. The application is strongest when the treating uro-oncologist's letter sets out (1) the specific prostate cancer disease state being treated (mCRPC, nmCRPC, mCSPC, or nmCSPC with high-risk biochemical recurrence under the November 2023 FDA label extension), (2) the supporting evidence for that disease state (PSA trajectory, imaging, prior therapy timeline), (3) confirmation of medical or surgical castration status, with the GnRH agonist in use named (leuprolide most commonly), (4) the rationale for selecting Xtandi over locally available generic enzalutamide or other ARPIs (abiraterone acetate with prednisone, apalutamide, darolutamide) where the patient and physician have specifically chosen brand US-sourced product, (5) drug-drug interaction screening, particularly for strong CYP2C8 inhibitors and CYP3A4 inducers, and (6) seizure-risk screening given Xtandi's seizure signal across the class.

A complete Form 12A application includes the clinical justification letter from the treating Registered Medical Practitioner, the prescription showing the RMP's NMC registration number and the quantity required (160 mg daily, taken as 4 x 40 mg capsules, 4 x 40 mg tablets, or 2 x 80 mg tablets), a patient identifier with supporting medical records, product details (Xtandi as enzalutamide, manufacturer Astellas Pharma US under co-promotion with Pfizer, brand US-sourced product, requested quantity not exceeding 100 average doses per application per the second proviso to Rule 36), the dispensing facility's drug licence, and a chain-of-custody plan from the US specialty pharmacy through the importer to the receiving Indian pharmacy.

Where Xtandi gets dispensed in India

Xtandi is a room-temperature stable oral capsule or tablet (storage 20-25 degrees Celsius, with excursions permitted 15-30 degrees Celsius). Cold-chain capability is not required; what matters is uro-oncology and medical-oncology depth and a hospital pharmacy or CDSCO-licensed importer able to carry the Rule 36 paperwork. The Indian institutions that fit this profile include:

- **Tata Memorial Centre, Mumbai.** India's oldest and largest cancer institute, anchor of the National Cancer Grid, with active uro-oncology disease-management group.
- **All India Institute of Medical Sciences (AIIMS), New Delhi.** Apex public-sector institution with established uro-oncology and medical-oncology practice.
- **Apollo Hospitals (Chennai, Delhi, Bangalore, Hyderabad, Kolkata).** Large oncology programmes with dedicated international patient services, JCI and NABH accredited.
- **Fortis Memorial Research Institute, Gurgaon; Fortis Mulund, Mumbai; Medanta - The Medicity, Gurgaon; Kokilaben Dhirubhai Ambani Hospital, Mumbai; MGM Healthcare, Chennai; Manipal Hospitals, Bangalore; Christian Medical College (CMC), Vellore.** Tertiary uro-oncology and medical-oncology programmes with active prostate-cancer caseloads.

For patients outside the major metros, co-management with a uro-oncologist or medical oncologist at one of the centres above is the practical route, with refills routed through that hospital's import pharmacy or a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore. A monthly 120-capsule (40 mg) bottle aligns with a 30-day course at the standard 160 mg daily dose; quarterly refill cadences are feasible once the patient is established.

Real cost picture for Xtandi in India

US wholesale acquisition cost for brand Xtandi as of 2024-2025 disclosures is approximately USD 14,000 to USD 15,000 per 120-capsule (40 mg) bottle, which represents one month of therapy at the standard 160 mg daily dose. Astellas published a WAC of USD 14,332.47 per 120-capsule package in a May 2024 Pfizer co-prescriber disclosure, with subsequent 2025 disclosures trending toward USD 15,000. A 12-month course at WAC totals approximately USD 165,000

to USD 180,000 before any logistics, coordination, or country-specific markups. With the rupee floating against the dollar in the 94 to 95 INR per USD range in May 2026, a monthly drug cost of approximately USD 14,500 converts to approximately INR 13.7 lakh per month, or roughly INR 1.6 crore to INR 1.7 crore per year.

This is materially higher than the cost of locally available generic enzalutamide, and Reserve Meds is explicit with patients on the cost differential at intake. International logistics for an ambient-shipped oral product typically runs USD 300 to USD 550 per refill (approximately INR 28,000 to INR 52,000). The Astellas Pharma Support Solutions copay and patient assistance programmes are US-only and do not extend to international cases. Star Health, HDFC ERGO, ICICI Lombard, Niva Bupa, Apollo Munich, and Care Health handle named-patient brand-import cases case by case; none reimburse a Rule 36 brand personal import where a locally registered alternative exists as a standard line item, and many will direct the patient toward the locally registered version. The Union Budget 2026-27 expanded customs duty exemption on a set of named cancer medicines; the specific HSN code and exemption status is confirmed at the documentation stage. CGHS provides for non-formulary anti-cancer drugs to be considered case by case by an Expert Committee under the Special DG (DGHS), with stricter constraints where a DCGI-registered or locally registered alternative is available. Cash-pay is the default operating posture for brand US-sourced Xtandi in India.

Typical timeline for Xtandi in India

Xtandi is room-temperature stable, which keeps the modality-adjusted timeline at the simpler end of the country module range. The typical end-to-end timeline for a first Rule 36 import is 2 to 4 weeks: the Form 12B permit is issued on a documented priority basis (often 1 to 2 days at the DCGI office once documentation is complete), 5 to 10 days for US-side procurement through the Astellas specialty pharmacy network (Optum, CVS Specialty, Accredo, with the exact roster set by the manufacturer), and 3 to 5 days for ambient air freight and Indian customs clearance at Delhi, Mumbai, Bangalore, Chennai, or Hyderabad. Repeat monthly refill cycles for an established patient typically compress to 2 to 3 weeks because the Form 12A dossier and the procurement path are already in place. Quarterly cadences are feasible once the uro-oncologist confirms supply alignment with PSA and toxicity monitoring visits. Median treatment duration in the pivotal trials ranged from approximately 14 to 35 months across the disease states, with longer durations seen in earlier-stage indications.

What your physician needs to provide

The treating uro-oncologist's clinical justification letter is the cornerstone of the Form 12A package. For brand US-sourced Xtandi specifically, the letter typically addresses:

- **Mechanism and FDA indications.** Enzalutamide is an oral androgen receptor pathway inhibitor that blocks AR signaling at multiple steps. FDA approval history: 31 August 2012 for mCRPC post-docetaxel; 10 September 2014 for chemotherapy-naive mCRPC; July 2018 for nmCRPC; December 2019 for mCSPC; 16 November 2023 for nmCSPC with biochemical recurrence at high risk for metastasis.
- **Specific disease state and supporting evidence.** The letter identifies which of the four FDA-approved disease states applies, with the supporting PSA, imaging, and prior-therapy documentation.
- **Castration status.** Concomitant medical castration with a GnRH agonist (leuprolide most commonly) in castration-sensitive disease states, or confirmed prior bilateral orchiectomy. Continued medical castration alongside Xtandi in castration-resistant states.
- **Brand-versus-generic rationale.** The patient and physician have specifically requested brand US-sourced product for documented sourcing assurance, indication-coverage, or formulary-appeal reasons; locally registered generic enzalutamide has been considered and the choice of brand has been recorded.
- **Dosing plan.** 160 mg orally once daily, taken as 4 x 40 mg capsules, 4 x 40 mg tablets, or 2 x 80 mg tablets, with or without food. Dose modifications permitted to 120 mg or 80 mg daily, with interruption for up to one week, in the

event of Grade 3 or higher adverse reactions. Strong CYP2C8 inhibitor co-administration triggers reduction to 80 mg daily where unavoidable.

- **Monitoring plan.** Blood pressure monitored regularly. Low threshold for neurologic evaluation for seizure (occurred in roughly 0.6 percent across eight randomized trials) or posterior reversible encephalopathy syndrome (PRES). Periodic liver function tests. Fall and fracture risk assessment, particularly in older patients and those with osteoporosis history. Permanent discontinuation in patients who develop a seizure during treatment.
- **Physician registration.** Active NMC registration in urology, uro-oncology, or medical oncology, with state-council registration where required.
- **Pharmacovigilance acknowledgement.** The Pharmacovigilance Programme of India (PvPI) coordinated by the Indian Pharmacopoeia Commission is referenced; adverse event reporting through PvPI stays with the prescribing physician.

Common questions about Xtandi in India

Generic enzalutamide is available in India. Why brand US-sourced Xtandi?

Generic enzalutamide is a legitimate option that your uro-oncologist may recommend, and many Indian patients use it. Patients who choose brand US-sourced Xtandi through Rule 36 typically do so for one of three reasons: indication lag (the November 2023 FDA approval for nmCSPC with high-risk biochemical recurrence is not uniformly reflected in the Indian label or in local generic positioning), sourcing assurance (documented DSCSA chain of custody for US-manufactured originator product), or formulary or reimbursement workaround. Reserve Meds does not promote brand over generic. The choice is made by the patient and the treating physician.

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover this?

Each plan handles named-patient imports case by case. None reimburse a Rule 36 brand personal import as a standard line item when a locally registered alternative exists. Some may direct the patient toward generic enzalutamide. We supply the documentation that lets your insurer evaluate; the claim itself is filed by you or your hospital. Cash-pay is the default operating posture for brand US-sourced Xtandi.

Will CGHS or ESIC cover Xtandi?

CGHS provides for non-formulary anti-cancer medicines to be considered by an Expert Committee under the Special DG (DGHS), case by case. Where a DCGI-registered or locally manufactured alternative is available (as is true for enzalutamide in India), the Expert Committee review is stricter. ESIC's formulary is narrower. Neither scheme is structured for routine brand-personal-import reimbursement; check eligibility with your CGHS Wellness Centre or ESIC dispensary before assuming coverage.

Is there a comparator ARPI?

Within the ARPI class, abiraterone acetate (Zytiga) with prednisone, apalutamide (Erleada), and darolutamide (Nubeqa) are the most directly substitutable agents. Class selection depends on disease state, comorbidities, CNS exposure considerations (darolutamide has a lower CNS penetration profile, which some clinicians weight for patients with seizure history), and drug-drug interaction profile. The choice between agents is a clinical decision your uro-oncologist makes; Reserve Meds does not influence the prescribing choice.

What is the safety profile?

The most common adverse reactions include fatigue, back pain, hot flush, constipation, arthralgia, decreased appetite, diarrhoea, and hypertension. Falls and fractures occur at increased frequency versus placebo. Seizure is the most clinically

distinctive risk (roughly 0.6 percent across eight randomized trials, higher in patients with predisposing factors). PRES has been reported. The label directs permanent discontinuation in patients who develop a seizure during treatment.

How long does treatment continue?

Continuous daily dosing until disease progression or unacceptable toxicity. There is no fixed-duration regimen. Median treatment duration in the pivotal trials ranged from approximately 14 to 35 months depending on the disease state, with longer durations in earlier-stage indications.

Where Reserve Meds fits in Xtandi cases

Reserve Meds is a US-based concierge coordinator. We do not replace your uro-oncologist, CDSCO, or your dispensing pharmacy. For brand US-sourced Xtandi specifically, we orchestrate procurement through the Astellas US specialty pharmacy network (Optum, CVS Specialty, Accredo) with full DSCSA chain-of-custody documentation, prepare the documentation kit your Indian uro-oncologist needs to file the Form 12A application (with the multi-state-indication template, brand-vs-generic rationale framework, drug-drug interaction screen, and PvPI acknowledgement pre-built), align the ambient air-freight shipment plan with the Indian importer or hospital pharmacy, and assign a single named coordinator who carries the case through the monthly or quarterly refill cadence. Brand-cash-pay framing is explicit; cost expectations are anchored at the WAC reference rather than at locally registered generic pricing. No prior Reserve Meds closed-case experience for Xtandi as of this page date; standard Rule 36 coordination applies. Operational notes will be added as cases land.

Next step

If your Indian uro-oncologist has identified Xtandi as the right ARPI for your prostate cancer disease state and you have decided on brand US-sourced product through a documented DSCSA chain of custody, add your case to our waitlist. We will confirm eligibility within 24 to 48 hours and send the documentation kit to your physician.

Reserved for you.

This guide is informational, not medical or legal advice. The CDSCO Rule 36 pathway requires an NMC-registered physician's clinical judgment; Reserve Meds is the coordinator, not the prescriber.

Review and oversight. Content on this page is reviewed by Reserve Meds's 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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