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Xtandi access in Saudi Arabia through the SFDA Personal Importation Program

How Saudi men with prostate cancer (mCRPC, nmCRPC, mCSPC, or nmCSPC with high-risk biochemical recurrence) source Xtandi (enzalutamide), what the PIP application package looks like, and where Reserve Meds fits.

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

Quick orientation

Xtandi is the brand name for enzalutamide, an oral once-daily androgen receptor pathway inhibitor (ARPI) co-developed by Astellas and Pfizer and first approved by the US FDA on 31 August 2012. Across subsequent label expansions, Xtandi is now FDA-approved across four prostate cancer states: metastatic castration-resistant prostate cancer (mCRPC), non-metastatic castration-resistant prostate cancer (nmCRPC), metastatic castration-sensitive prostate cancer (mCSPC), and most recently, on 16 November 2023, non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis. Xtandi is registered in Saudi Arabia through Astellas's local affiliate, but indication lag, formulary positioning, and sourcing-assurance concerns drive Saudi men to reach for US-sourced Xtandi through the SFDA Personal Importation Program (PIP). Reserve Meds coordinates the US-side sourcing and the documentation kit your oncologist or urologist needs. Reserved for you.

Why Saudi men reach for Xtandi through the named-patient pathway

Xtandi is registered with the SFDA, which sets it apart from most drugs on the Reserve Meds matrix. Yet Saudi men still reach for Xtandi through cross-border channels for three specific reasons that map to the country module's framing of the three structural access patterns. First, indication lag: the most recent FDA approval (nmCSPC with high-risk biochemical recurrence, 16 November 2023) is not uniformly reflected in the local SFDA label yet. Patients whose oncologist wants Xtandi at this earlier disease state may find that the local label still restricts use to mCRPC or mCSPC. Where the patient and treating physician align on the FDA-supported earlier-line use and the local label has not caught up, PIP is the legitimate route to source the US-labeled product for that specific indication. Second, formulary exclusion: even where Xtandi is locally registered, public-sector hospital formularies and private insurer formularies in the Kingdom may exclude or restrict it (oncology budgets are constrained, ARPI alternatives may be preferred on cost grounds). Third, sourcing assurance: sophisticated cash-pay patients prefer US-sourced product through a documented DSCSA chain of custody over locally registered stock from less transparent supply lines.

Saudi Arabia carries a meaningful prostate cancer caseload across the major tertiary oncology centres, and oncology and urologic oncology service depth at KFSH&RC, KAMC, and the major HMG centres has grown under Vision 2030's Health Sector Transformation Program. Xtandi sits in the recurring oncology drug-name inquiry pattern alongside abiraterone, apalutamide, and darolutamide, with the multi-indication framing across four FDA-approved disease states the load-bearing differentiator.

The SFDA Personal Importation Program for Xtandi

The Saudi pathway for a KSA-licensed oncologist or urologist to obtain US-sourced Xtandi is the SFDA Personal Importation Program. PIP allows a SCFHS-licensed physician to request the import of a specific medicine for a specific named patient when the medicine is approved by a recognised reference authority (the FDA, EMA, MHRA, PMDA, and Health Canada all carry Xtandi) and a clinically equivalent locally registered alternative is not suitable for the patient.

Applications are filed through the dispensing institution's import pharmacy and routed through the SFDA Ghad digital platform.

For Xtandi specifically, the clinical-justification angle that anchors the application is the prostate cancer disease state with FDA-label indication alignment. The PIP application is strongest when the oncologist's or urologist's letter sets out (1) the prostate cancer diagnosis with the specific disease state explicitly named (mCRPC, nmCRPC, mCSPC, or nmCSPC with high-risk biochemical recurrence), (2) the staging documentation and disease trajectory (imaging, PSA kinetics, prior systemic therapy if any), (3) the FDA-label indication for the specific disease state and approval date (12 August 2012 for post-docetaxel mCRPC; 10 September 2014 for chemo-naïve mCRPC; July 2018 for nmCRPC; December 2019 for mCSPC; 16 November 2023 for nmCSPC with high-risk BCR), (4) why a locally registered alternative is not suitable (which for an indication-lag case is typically that the local label does not cover the FDA-approved earlier-line state for which the patient is being treated), and (5) the planned androgen-deprivation backbone (GnRH agonist such as leuprolide, or prior bilateral orchiectomy) in castration-sensitive disease states.

A complete PIP package typically includes:

- Clinical justification letter from the treating oncologist or urologist (prostate cancer diagnosis with specific disease state, FDA-label indication alignment, why Xtandi, why a locally registered alternative is not suitable)
- Imaging and PSA history supporting the disease-state designation
- Treating physician SCFHS license verification in medical oncology, urologic oncology, or urology
- Patient identifier in SFDA-required format
- Product details: Xtandi 40 mg soft gelatin capsules or 40 mg / 80 mg film-coated tablets, bottle quantity for the requested supply, manufacturer Astellas Pharma US, Inc., country of origin USA, requested quantity per refill cycle, lot, and expiry
- Destination dispensing facility license
- Chain-of-custody plan from the US specialty pharmacy through the importer to the receiving Saudi pharmacy
- Post-import pharmacovigilance acknowledgement through the SFDA National Pharmacovigilance Center

Approval timelines for routine PIP cases run 10 to 21 business days. Because Xtandi is a long-established reference-authority drug with a well-documented multi-indication FDA label, established tertiary oncology and urology centres typically receive routine-track review. Indication-lag cases (nmCSPC with high-risk BCR being the most recent and least uniformly covered locally) can extend to 4 to 6 weeks where the SFDA reviewer is reconciling the FDA label expansion against the local label.

Where Xtandi gets dispensed in Saudi Arabia

Xtandi is a room-temperature stable oral capsule or tablet (storage 20 to 25 degrees Celsius with permitted excursions to 15 to 30 degrees Celsius) with no reconstitution and no cold chain. The capability that matters is oncology or urologic oncology service depth, particularly the ability to manage the GnRH backbone, monitor for ARPI-specific adverse events (seizure, falls, fractures, hypertension), and coordinate bone-targeted therapy in metastatic disease. The Saudi institutions with this profile are:

- **King Faisal Specialist Hospital and Research Centre (KFSH&RC).** Tertiary and quaternary referral centre with deep oncology, urologic oncology, and supportive care services across Riyadh, Jeddah, and Madinah. In-house import pharmacy handles PIP filings as routine workflow.
- **King Abdulaziz Medical City (KAMC) and the MNGHA network.** Major tertiary oncology and urology services in Riyadh and Jeddah.
- **King Saud University Medical City (KSUMC) and KSAU-HS affiliated centres.** Academic medical centres with oncology and urology programs.

- **Dr. Sulaiman Al Habib Medical Group (HMG).** Large private hospital network with oncology and urology depth across multiple Riyadh, Jeddah, and Eastern Province facilities, and routine PIP activity for Xtandi.
- **Saudi German Health, Dr. Soliman Fakeeh Hospital (Jeddah), and Dallah Hospital (Riyadh).** Private referral centres with oncology and urology services.

Because Xtandi is an oral take-home medication, refills typically dispense through the hospital outpatient pharmacy or an SFDA-licensed specialty importer's pharmacy, with the patient picking up the bottle. For patients in the Eastern Province, Madinah, or other regions, the practical pattern is co-management with a SCFHS-licensed urologist or oncologist at one of the Riyadh or Jeddah centres, with refills routed through that hospital's import pharmacy.

Real cost picture for Xtandi in Saudi Arabia

The US wholesale acquisition cost (WAC) for Xtandi is approximately USD 13,650 to USD 15,005 per 120-capsule (40 mg) bottle, which represents one month of therapy at the standard 160 mg daily dose. Astellas published a WAC of approximately USD 14,332 per 120-capsule package in May 2024, with 2025 disclosures trending toward the USD 15,000 mark. At the SAR peg of approximately 3.75 SAR to 1 USD, that converts to a per-month drug-cost working range of approximately SAR 51,200 to SAR 56,300. A 12-month course at WAC totals roughly USD 165,000 to USD 180,000 (approximately SAR 619,000 to SAR 675,000) before any logistics, coordination, or country-specific markups.

International logistics for an ambient-shipped oral capsule typically runs USD 300 to USD 600 per refill (approximately SAR 1,125 to SAR 2,250), the lowest end of the country module logistics range because cold-chain insulation and temperature loggers are not required. SFDA permit and importer handling fees are itemised separately. The Reserve Meds concierge fee appears as its own line on every firm quote. Astellas Pharma Support Solutions copay and patient assistance are US-only and do not extend to Saudi cases. Bupa Arabia, Tawuniya, and MedGulf handle prostate cancer therapy reimbursement decisions case by case, with the locally registered Xtandi being a more common formulary entry than the US-sourced PIP equivalent. For PIP cases driven by indication lag or formulary exclusion, cash-pay is the default operating posture.

Typical timeline for Xtandi in Saudi Arabia

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 PIP import is 4 to 7 weeks: 10 to 21 business days for routine SFDA review at an established centre (slightly longer for indication-lag cases where SFDA is reconciling the FDA label against the local label), 5 to 7 days for US-side specialty pharmacy procurement of the 120-capsule bottle quantity, and 3 to 5 days for ambient air freight and Saudi customs clearance. Repeat refill cycles for an established patient typically compress to 2 to 3 weeks because the PIP dossier, the prescriber relationship, and the US-side procurement path are already in place. Treatment is continuous daily dosing until disease progression or unacceptable toxicity, and median treatment duration in the pivotal trials ranged from approximately 14 to 35 months depending on the disease state, so a monthly refill cadence is the steady-state norm.

What your physician needs to provide

The treating oncologist's or urologist's clinical justification letter is the cornerstone of the SFDA PIP package. For Xtandi specifically, the letter typically addresses:

- **Mechanism and FDA indication.** Enzalutamide is an oral small-molecule androgen receptor pathway inhibitor that blocks AR signaling at multiple steps. FDA-approved across four prostate cancer states: mCRPC (initial approval 31 August 2012, expanded 10 September 2014), nmCRPC (July 2018), mCSPC (December 2019), and nmCSPC with high-risk biochemical recurrence (16 November 2023).

- **Disease-state designation.** Explicit naming of the FDA-approved indication that matches the patient's clinical picture, with PSA history, imaging findings, and prior therapy outcomes.
- **Dosing plan.** 160 mg orally once daily (4 x 40 mg capsules, 4 x 40 mg tablets, or 2 x 80 mg tablets), with or without food. Across all four FDA-approved indications, the daily dose is the same.
- **Backbone therapy.** In castration-sensitive states (mCSPC, nmCSPC with high-risk BCR), Xtandi is administered together with a GnRH agonist such as leuprolide or with prior bilateral orchiectomy. In castration-resistant states (mCRPC, nmCRPC), the patient continues medical castration alongside Xtandi.
- **Dose modifications.** Permitted reduction to 120 mg or 80 mg daily for Grade 3 or higher adverse reactions; dose reduction to 80 mg daily if a strong CYP2C8 inhibitor is required co-administered; strong CYP3A4 inducers should be avoided.
- **Monitoring plan.** Blood pressure monitoring; low threshold for neurologic evaluation (seizure, 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 license.** Active SCFHS registration in medical oncology, urologic oncology, or urology.

Common questions about Xtandi in Saudi Arabia

Xtandi is registered locally. Why am I sourcing through PIP?

Three reasons are common in Saudi cases. First, indication lag: the latest FDA expansion (nmCSPC with high-risk biochemical recurrence in November 2023) is not uniformly reflected in the local SFDA label yet, and your oncologist may want Xtandi at this earlier disease state. Second, formulary exclusion: even where Xtandi is locally registered, your insurer or hospital formulary may exclude or restrict it. Third, sourcing assurance: you prefer US-sourced product through a documented DSCSA chain of custody.

Will Bupa Arabia, Tawuniya, or MedGulf cover this?

For locally registered indications, insurers typically prefer locally registered Xtandi over US-sourced PIP product. For indication-lag cases (nmCSPC with high-risk BCR), coverage decisions are case by case, and the clinical justification letter is the cornerstone of any pre-authorisation request. We supply the documentation set; the claim sits with you or your hospital. Cash-pay is the default operating posture for PIP cases.

What is the safety profile?

The most common adverse reactions across the prostate cancer indications 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: seizure occurred in roughly 0.6 percent of Xtandi-treated patients across eight randomised trials, with higher rates in patients with predisposing factors. Posterior reversible encephalopathy syndrome (PRES) has been reported. The label directs permanent discontinuation in patients who develop a seizure during treatment.

Should I use abiraterone, apalutamide, or darolutamide instead?

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

How long do I stay on Xtandi?

Treatment is 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 seen in earlier-stage indications.

What about drug-drug interactions?

Strong CYP3A4 inducers (such as rifampin or phenytoin) reduce enzalutamide exposure and should be avoided where possible. If a strong CYP2C8 inhibitor is required co-administered, the Xtandi dose should be reduced to 80 mg daily. Reserve Meds runs drug-drug interaction screening with your full medication list as part of the onboarding flow.

Where Reserve Meds fits in Xtandi cases

Reserve Meds is a US-based concierge coordinator. We do not replace your oncologist or urologist, SFDA, or your dispensing pharmacy. For Xtandi specifically, we orchestrate the US-side sourcing through a DSCSA-compliant specialty pharmacy network that holds Xtandi inventory in the appropriate bottle quantities, prepare the documentation kit your Saudi physician needs to file the PIP application (with the disease-state designation, FDA-label indication alignment, dosing plan, backbone therapy, and monitoring plan templates pre-built for each of the four prostate cancer indications), align the ambient air-freight shipment plan with the Saudi importer, and assign a single named coordinator who carries the case through the first month and the recurring monthly refill cadence. Xtandi is one of the higher-volume drug-name inquiries we expect in the prostate cancer category alongside abiraterone and apalutamide. No prior Reserve Meds closed-case experience for Xtandi as of this page date; standard NPP coordination applies.

Next step

If you have a prostate cancer diagnosis in any of the four FDA-approved disease states (mCRPC, nmCRPC, mCSPC, or nmCSPC with high-risk biochemical recurrence) and your Saudi oncologist or urologist has identified Xtandi as the right next step, 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 SFDA Personal Importation Program requires a SCFHS-licensed 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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