Akeega access in Saudi Arabia

How Saudi patients with BRCA-mutated metastatic prostate cancer reach Akeega (niraparib plus abiraterone acetate) through the SFDA Personal Importation Program.

Quick orientation

Akeega is the first fixed-dose combination oral tablet of niraparib (a PARP inhibitor) and abiraterone acetate (a CYP17 androgen-biosynthesis blocker), approved by the U.S. FDA on August 11, 2023 for BRCA-mutated metastatic castration-resistant prostate cancer (mCRPC) and expanded in December 2025 to BRCA2-mutated metastatic castration-sensitive prostate cancer (mCSPC). Both indications require BRCA mutation confirmation through an FDA-approved companion diagnostic such as FoundationOne CDx. In Saudi Arabia, Akeega has no SFDA marketing authorization. Patients in the Kingdom who have completed BRCA testing and have a treating oncologist at KFSH&RC, KAMC, MNGHA, HMG, or Saudi German reach Akeega through the SFDA Personal Importation Program (PIP). Reserve Meds is the U.S.-side coordinator. The treating oncologist owns the BRCA confirmation, the prescription, and the monitoring plan. Reserved for you.

Why BRCA-mutated prostate cancer patients in Saudi Arabia need Akeega via NPP

Three structural reasons drive the SFDA Personal Importation Program for Akeega. First, Akeega is not on the SFDA national drug registration list. The fixed-dose combination cannot be filled at a Saudi pharmacy through normal commercial channels. Even where separate niraparib (Zejula) and separate abiraterone (Zytiga or generics) are locally accessible, the single-tablet combination is not stocked. Second, the indication is gated by BRCA testing, and access to FDA- or EMA-recognized companion diagnostics has improved meaningfully in the Kingdom under the Vision 2030 genomics investment, but several patients arrive at the Akeega decision after testing through a U.S. or EU reference lab. The clinical decision sequence (BRCA confirmation, then treatment selection) precedes the regulatory mechanism. Third, the MAGNITUDE evidence base is specifically for the niraparib-plus-abiraterone-plus-prednisone regimen, and the simplicity of a single fixed-dose tablet over two separately prescribed and separately sourced medicines is a real adherence and monitoring advantage for treating oncologists. Patients and families managing other prostate cancer therapy elements at the same time often prefer the consolidated regimen.

The SFDA Personal Importation Program (PIP) for Akeega

SFDA's Personal Importation Program allows a KSA-licensed oncologist to request import of a specific medicine for a specific named patient when the medicine is approved by a recognized reference authority (FDA and EMA both apply to Akeega) and a locally registered alternative is not clinically suitable. For Akeega, the clinical-justification angle has three documentable pillars: the BRCA mutation confirmation through an FDA-approved companion diagnostic (FoundationOne CDx is the standard reference), the metastatic prostate cancer staging and prior-line history, and the rationale for the fixed-dose combination over separately prescribed niraparib and abiraterone.

The PIP application contains a clinical justification letter from the treating oncologist addressing the prostate adenocarcinoma diagnosis with ICD-10 coding (C61), the molecular pathology including the specific BRCA1 or BRCA2 deleterious or suspected deleterious variant, the staging (metastatic castration-resistant or, under the December 2025 expansion, BRCA2-mutated metastatic castration-sensitive), the prior-line history if any, the rationale for selecting Akeega over olaparib-plus-abiraterone (Lynparza plus Zytiga) or talazoparib-plus-enzalutamide (Talzenna plus Xtandi), and the requested dose. It includes Saudi Commission for Health Specialties (SCFHS) license verification for the prescribing medical oncologist or uro-oncologist. It includes the patient identifier in SFDA's required format. It includes product details (brand Akeega, INN niraparib plus abiraterone acetate, manufacturer Janssen Biotech, country of origin, the specific strength configuration, requested quantity, lot, and expiry). It includes the dispensing facility license. And it includes the chain-of-custody plan with heat-excursion logging.

Two PIP-file features matter for Akeega. First, the BRCA confirmation must be attached as a formal molecular pathology report from an accredited laboratory, not a summary statement. PIP reviewers expect to see the variant call. Second, the file should explicitly state that Akeega is co-administered with prednisone 10 mg orally once daily and, for mCSPC patients, that androgen deprivation therapy continues in parallel. The PIP application is for Akeega specifically; the prednisone and the GnRH analogue are sourced locally and do not flow through this file, but the treatment plan should be coherent in the letter.

Approval timelines for routine oncology cases at established institutions typically run 10 to 21 business days. Complex cases (first oncology PIP at the institution, novel BRCA variant calls, off-label dose modifications) can extend to 6 to 10 weeks.

Where Akeega gets dispensed in Saudi Arabia

For Akeega, the relevant institutional subset is centers with established medical oncology programs, molecular pathology infrastructure, and PIP-experienced import pharmacy operations. King Faisal Specialist Hospital and Research Centre (KFSH&RC) in Riyadh, Jeddah, and Madinah is the principal tertiary cancer referral setting in the Kingdom, with uro-oncology services, in-house molecular pathology, and routine PIP filings on oncology cases. King Abdulaziz Medical City (KAMC) and the broader MNGHA network in Riyadh and Jeddah have established medical oncology programs. King Saud University Medical City handles academic oncology referrals. Dr. Sulaiman Al Habib Medical Group (HMG) operates oncology services across its Riyadh, Jeddah, and Eastern Province facilities. Saudi German Health, Dr. Soliman Fakeeh Hospital in Jeddah, and Dallah Hospital in Riyadh round out the established private oncology set.

Because Akeega is a controlled-room-temperature oral solid product, the dispensing-facility list is wider than for cold-chain biologics. The relevant institutional capability is oncology care, BRCA-aware molecular pathology, and PIP-experienced import pharmacy operation. Tablets are dispensed to the patient who self-administers daily at home, on an empty stomach, with no food for at least one hour before or two hours after the dose.

Real cost picture for Akeega in Saudi Arabia

The U.S. wholesale acquisition cost for Akeega is approximately USD 19,193.60 for a 60-tablet bottle of the 100 mg niraparib plus 500 mg abiraterone acetate strength per Drugs.com pricing references, with patient-month cost in the order of USD 19,000 to USD 20,000 per 30-day supply at WAC. The full daily dose of 200 mg niraparib plus 1,000 mg abiraterone acetate requires two tablets of the 100 mg plus 500 mg strength.

For a Saudi PIP case, the cost stack has three line items. The drug cost reflects the bottles dispensed against the named-patient case, in the order of USD 19,000 to USD 20,000 per 30-day supply (approximately SAR 71,000 to SAR 75,000 at the SAR 3.75 to USD 1.00 peg). International logistics for an ambient-temperature oral oncology product run in the USD 300 to USD 700 range per shipment (approximately SAR 1,125 to SAR 2,625), reflecting standard pharmaceutical packaging with heat-excursion logging for transit through the Arabian Peninsula. There is no -80°C handling, no liquid-nitrogen requirement, and no validated insulated packaging beyond the manufacturer's tamper-evident DSCSA-compliant carton. Reserve Meds adds a transparent coordination fee per quote, shown separately.

Bupa Arabia, Tawuniya, and MedGulf Arabia handle named-patient oncology imports case-by-case. CADTH-calculated Canadian list-price equivalents place the 28-day Akeega cost near CAD 8,283, meaningfully below the U.S. WAC, which is occasionally referenced by Saudi payers in pre-authorization discussions. Cash-pay is the default operating posture for cross-border oncology access, with insurer reimbursement pursued after delivery where the plan permits.

Typical timeline for Akeega in Saudi Arabia

For a BRCA-mutated mCRPC or mCSPC patient with a treating oncologist at an established tertiary cancer center, the typical end-to-end window is 4 to 6 weeks from first inquiry to first dose. Reserve Meds intake and documentation kit delivery to the prescriber typically runs 24 to 48 hours. PIP filing preparation runs 3 to 7 business days because the BRCA molecular pathology report and the prior-line oncology history need to be assembled. SFDA review runs 10 to 21 business days for routine cases at established cancer centers, with extensions for first-time Akeega cases at the institution. U.S. sourcing and ambient international shipping of the manufacturer's bottles add 3 to 7 days from approval. Reorders run faster because the operational rails are in place; the second and third PIP cycle for the same patient typically runs 3 to 4 weeks end-to-end. Treatment continues until disease progression or unacceptable toxicity, with monthly reorders typical.

What your physician needs to provide

The treating oncologist's clinical justification letter is the cornerstone. For an Akeega case the letter should include the prostate adenocarcinoma diagnosis with histology and ICD-10 C61, the staging (metastatic, with sites of metastasis), the castration-resistant or castration-sensitive classification, the BRCA1 or BRCA2 deleterious or suspected deleterious variant call from FoundationOne CDx or an equivalent FDA-approved companion diagnostic with the molecular pathology report attached, the prior-line history if any (chemotherapy, androgen-axis agents, prior PARP exposure), the rationale for selecting Akeega over olaparib-plus-abiraterone or talazoparib-plus-enzalutamide, the requested dose (200 mg niraparib plus 1,000 mg abiraterone acetate orally once daily on an empty stomach, with prednisone 10 mg orally once daily), and the monitoring plan covering complete blood count (weekly for the first month, then monthly), blood pressure, liver function tests, serum potassium, and ongoing vigilance for myelodysplastic syndrome and acute myeloid leukemia which are PARP-class warnings.

The letter should explicitly acknowledge the MDS and AML warning from the FDA label, the abiraterone-class warnings on hypertension, hypokalemia, fluid retention, and adrenocortical insufficiency under stress, and the specific dose-modification logic for hematologic toxicity (niraparib can be reduced from 200 mg to 100 mg in two steps; abiraterone is generally held rather than reduced). Adverse-event reporting through the SFDA National Pharmacovigilance Center is the prescriber's responsibility throughout the treatment course.

Common questions about Akeega in Saudi Arabia

Will Bupa Arabia or Tawuniya cover this? Each plan handles named-patient oncology imports case-by-case. Some plans cover BRCA-targeted prostate cancer therapies on the formulary at meaningful levels; many require pre-authorization with the molecular pathology report and the clinical justification letter. Cash-pay is the default posture, with reimbursement pursued after delivery.

Do I need BRCA testing before initiation? Yes. The FDA label requires BRCA mutation confirmation before the first dose, through an FDA-approved companion diagnostic such as FoundationOne CDx. If your testing was done at a Saudi or international laboratory, the molecular pathology report needs to be reviewed for compatibility with the labeled requirement before the PIP file is opened.

What is the MDS and AML warning? Myelodysplastic syndrome and acute myeloid leukemia have been reported with niraparib and other PARP inhibitors, including fatal cases, and this risk is described in the FDA label as a warning. Long-term hematologic surveillance is part of the standard monitoring plan. The treating oncologist owns this monitoring.

Why Akeega versus separate niraparib and abiraterone? A single fixed-dose tablet simplifies administration and adherence relative to two separately prescribed and separately sourced medicines. The MAGNITUDE evidence base is specifically for the combination. The treating oncologist makes the selection between the fixed-dose combination, the olaparib-plus-abiraterone combination, the talazoparib-plus-enzalutamide combination, and other regimens.

Can I take Akeega with food? No. Per the FDA label, Akeega is taken on an empty stomach. No food should be consumed for at least one hour before or two hours after each dose. Abiraterone exposure increases significantly with food and that exposure increase is associated with toxicity. This is a patient-administration discipline, not a clinical-decision question.

Is Akeega a controlled substance? No. Niraparib and abiraterone acetate are not DEA-scheduled. The standard PIP pathway applies.

Where Reserve Meds fits in Akeega cases

Reserve Meds is the U.S.-side concierge coordinator. For an Akeega case in Saudi Arabia, Reserve Meds confirms eligibility and case fit including BRCA documentation review within 24 to 48 hours, sends the documentation kit to your treating oncologist, coordinates U.S. specialty pharmacy sourcing through Janssen's authorized limited-distribution channel (Onco360 is the principal partner), manages ambient-temperature international logistics with heat-excursion logging, and assigns a single named Concierge Patient Coordinator who stays with the patient and family across monthly reorders. Reserve Meds does not file the PIP application, does not prescribe, does not interpret BRCA results, and does not advise on the choice between PARP combinations. The clinical authority remains with the SCFHS-licensed oncologist. The regulatory authority remains with SFDA. The dispensing remains with the licensed Saudi hospital pharmacy.

Next step

If you have BRCA-mutated metastatic prostate cancer and the treating oncologist has discussed Akeega, the waitlist is the entry point. Reserve Meds responds within 24 to 48 hours with a documentation kit for your oncologist and an indicative cost range. The firm quote follows after BRCA documentation review and prescriber confirmation of the dose plan.

Reserved for you.