

[Skip to main content](#)

[Home](#) / [Drugs](#) / [Cobenfy](#) / [In Saudi Arabia](#)

Cobenfy access in Saudi Arabia

A first-in-three-decades muscarinic mechanism for adult schizophrenia, reached through the SFDA Personal Importation Program.

Quick orientation

Cobenfy (xanomeline and trospium chloride) is an oral fixed-dose combination approved by the US FDA in September 2024 for the treatment of schizophrenia in adults. It is the first medicine in a new pharmacologic class for schizophrenia in more than thirty years and the only FDA-approved antipsychotic that does not depend on dopamine D2 receptor blockade. In Saudi Arabia, Cobenfy is not yet registered with the Saudi Food and Drug Authority (SFDA). For Saudi families and treating psychiatrists who have reached the conclusion that a non-D2 mechanism is the right next step, the lawful route is the SFDA Personal Importation Program (PIP), supported by a US specialty pharmacy procurement chain and named-patient documentation prepared in coordination with the dispensing institution. Reserve Meds coordinates the US sourcing, the documentation kit your physician will need, and the international logistics on the family's behalf, while clinical decisions stay with your treating psychiatrist. Reserved for you.

Why patients in Saudi Arabia need Cobenfy via the named-patient pathway

The access gap for Cobenfy in the Kingdom is structural, not transient. Cobenfy received FDA approval in late 2024. As of this page's review date, the Bristol Myers Squibb (BMS) commercial filing footprint with the SFDA is not yet in place, so the drug is not on the national drug registration list. The local antipsychotic formulary remains dominated by first-generation and second-generation D2 antagonists, which is the therapeutic class that has shaped psychiatric practice in the Kingdom for decades. For patients who have cycled through two or three lines of D2 antagonists without adequate response, or who have not tolerated D2 blockade because of extrapyramidal symptoms, tardive dyskinesia, metabolic syndrome, prolactin elevation, or sedation, the conventional Saudi formulary does not contain a mechanistically distinct option.

Cobenfy fills that gap precisely. Its therapeutic effect arises from selective M1 and M4 muscarinic acetylcholine receptor activity in the brain (الفصام, schizophrenia, is the indication, and the muscarinic mechanism is the clinical novelty). For families coordinating care for an adult relative whose psychiatrist has documented prior-line failure or intolerance, Cobenfy is not a marginal improvement on an existing class. It is the only available representative of a different class. The SFDA Personal Importation Program is explicitly designed for cases of this shape: a drug approved by a recognized reference authority (in this case the US FDA), where a clinically equivalent locally registered alternative is not suitable for the patient.

The SFDA Personal Importation Program for Cobenfy

The SFDA Personal Importation Program allows a KSA-licensed physician to request import of a specific medicine for a specific named patient when the medicine is approved by a recognized reference authority (typically the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and a clinically equivalent locally registered alternative is not suitable. The framework explicitly contemplates psychiatry and neurology specialty therapies. Applications are filed through the dispensing institution's import pharmacy and reviewed by SFDA's Drug Sector. The agency increasingly routes named-patient transactions through its Ghad digital platform.

For a Cobenfy case, the application package contains the clinical justification letter from the treating psychiatrist (diagnosis with ICD-10 coding, prior antipsychotic trials with documented outcomes, the clinical rationale for moving to a non-D2 muscarinic agent, the requested dose and duration), Saudi Commission for Health Specialties (SCFHS) license verification, an SFDA-format anonymized patient identifier tied to the hospital record, product details (Cobenfy capsule strengths, BMS as manufacturer of record, country of origin, pack size, requested quantity, lot, expiry), the destination dispensing facility license, and a chain-of-custody plan covering US release through international transit to the receiving Saudi pharmacy.

The clinical-justification angle specific to Cobenfy is documented prior-line failure or intolerance on D2 antagonists. The treating psychiatrist's letter typically names the antipsychotics already trialed, the outcomes observed (insufficient symptom control, EPS, tardive dyskinesia, metabolic decompensation, prolactin elevation, sedation, or non-adherence driven by these), and the clinical reasoning for a mechanistically distinct option. The titration plan (50 mg / 20 mg twice daily on days 1 to 2, escalating to 100 mg / 20 mg twice daily through day 7, then 125 mg / 30 mg twice daily on day 8 and onward as tolerated) and the monitoring plan (liver enzymes, blood pressure and heart rate, urinary retention assessment particularly in male and geriatric patients, and surveillance for biliary or pancreatic symptoms) belong in the same letter.

Approval timelines for routine cases of this type, at an institution with established PIP workflow, typically run 10 to 21 business days. A first-time importer, a non-Saudi prescribing physician undergoing license renewal, or a request that triggers SFDA queries on the novel mechanism can extend the timeline to six to ten weeks. SFDA does not publish guaranteed turnaround times, so the planning posture is case-by-case.

Where Cobenfy gets dispensed in Saudi Arabia

Cobenfy is an ambient-temperature oral capsule, which means the dispensing-facility shortlist is broader than it would be for a cold-chain biologic. The institutions that handle SFDA named-patient imports as established workflow and have psychiatric specialty capability include King Faisal Specialist Hospital and Research Centre (KFSH&RC, with operations in Riyadh, Jeddah, and Madinah), King Abdulaziz Medical City (KAMC) and the Ministry of National Guard Health Affairs network (MNGHA) in Riyadh and Jeddah, King Saud University Medical City (KSUMC) and the broader King Saud bin Abdulaziz University for Health Sciences (KSAU-HS) affiliated centers, Dr. Sulaiman Al Habib Medical Group (HMG, the largest private hospital network in the Kingdom), Saudi German Health, Dr. Soliman Fakeeh Hospital in Jeddah, and Dallah Hospital in Riyadh.

For families based outside Riyadh and Jeddah, the practical route is to partner with an SFDA-licensed specialty importer based in one of those two cities, which handles the SFDA filing and customs clearance. The importer then transfers the drug to the dispensing facility under the institutional license. Because Cobenfy capsules are room-temperature stable with no reconstitution and no temperature-monitored handoff, the logistics burden lives at customs documentation and SFDA registration evidence rather than at cold-chain control.

Real cost picture for Cobenfy in Saudi Arabia

The transparent cost build for a Cobenfy case in the Kingdom has three line items. First, the underlying US drug cost. Cobenfy's US wholesale acquisition cost is published by BMS at approximately USD 1,887 for a 30-day supply, or roughly SAR 7,075 at the 3.75 SAR per 1 USD currency peg, with annual cost of therapy near USD 22,500 (approximately SAR 84,375). Second, international logistics, which for an ambient-temperature oral product run in the SAR 1,500 to SAR 3,000 range (USD 400 to USD 800) per shipment because no validated cold-chain shipper or temperature data logger is needed. Third, regulatory documentation handling at the Saudi end and the Reserve Meds coordination fee, which are quoted as named line items rather than bundled.

On the insurance side, Bupa Arabia, Tawuniya (The Company for Cooperative Insurance), and MedGulf Arabia handle named-patient imports case-by-case under the Council of Cooperative Health Insurance framework. Some plans reimburse fully when the medicine appears on the insurer's formulary even though not stocked at a particular hospital, others reimburse a percentage, and many require pre-authorization with the clinical justification letter attached. Cash-pay is the default operating posture for cross-border access, with reimbursement, where available, sought after delivery through the patient's own claim. Reserve Meds quotes an indicative range based on the initial intake, then a transparent firm quote with each line item shown separately. Nothing is bundled or hidden.

Typical timeline for Cobenfy in Saudi Arabia

End to end, a routine Cobenfy case at a tertiary center with established PIP workflow typically clears 10 to 21 business days of SFDA review, plus three to seven days for US specialty pharmacy intake and outbound preparation, plus four to seven

days for international transit and customs clearance. That puts a realistic end-to-end planning window of three to five weeks for a routine case. Because Cobenfy is ambient-temperature, the international transit leg does not require a validated cold-chain shipper, which removes a common source of multi-day delay. The principal scheduling variable is the SFDA review, which for a relatively new mechanism may run longer for a first-time case at a given institution and faster for the second case at the same institution because the operational rails are already in place. The titration schedule begins on the day of dispense and runs across days 1 to 8 before the patient reaches the 125 mg / 30 mg target maintenance dose, so the families' calendar should account for the titration week as well as the import window.

What your physician needs to provide

The cornerstone document is the clinical justification letter, signed by the treating psychiatrist under their active SCFHS license. For Cobenfy, the letter typically covers the schizophrenia diagnosis with ICD-10 coding, the prior antipsychotic trials with named medicines and documented outcomes, the specific tolerability or response gap that motivates a non-D2 muscarinic agent, the requested dose and titration schedule, the monitoring plan (LFTs at baseline and as clinically indicated, blood pressure and heart rate tracking, urinary retention assessment particularly in male and geriatric patients, and surveillance for biliary disease and pancreatitis), and the planned course length. Because schizophrenia is chronic, the course is described as continuous maintenance rather than as a fixed cycle.

The treating physician's SCFHS registration must be active for the full requested treatment course because PIP authority is physician-license-tied. The dispensing facility's institutional pharmacy license is the second pillar of the application and authorizes the receiving pharmacy to accept the imported drug. Saudization (Nitaqat) does not change the framework, but if a non-Saudi prescribing psychiatrist is in license renewal at the time of filing, confirming SCFHS license status before submission is good practice. Reserve Meds supplies the physician documentation kit, including the SFDA adverse-event reporting reference so the treating physician has the pharmacovigilance framework on hand from day one. Reserve Meds does not file adverse-event reports; that responsibility sits with the SCFHS-licensed treating physician.

Common questions about Cobenfy in Saudi Arabia

Will Bupa Arabia, Tawuniya, or MedGulf cover this?

Each plan handles named-patient imports case-by-case. Cash-pay is the default. Reserve Meds supplies the documentation that lets the insurer assess; the claim is yours or your hospital's to file after delivery.

Will my Ministry of Health-employed psychiatrist's letter be sufficient if SFDA flags the case?

Yes. Public-sector psychiatrists at KFSH&RC, KAMC, MNGHA, and Ministry of Health hospitals have full signing authority on PIP applications under their SCFHS license. Private-sector psychiatrists at HMG, Saudi German, Fakeeh, Dallah, and similar institutions also sign PIP applications under their institutional license.

Is Cobenfy a controlled substance?

No. Cobenfy is not a DEA-scheduled drug. It is in scope for Reserve Meds cross-border coordination. We do not handle DEA Schedule I-V controlled substances under any circumstance.

Can my family member take Cobenfy at home?

Cobenfy is an oral capsule and once dispensed from the licensed Saudi pharmacy, it is taken at home on the prescribed twice-daily schedule, at least one hour before a meal or at least two hours after a meal. Capsules are not to be opened, crushed, or chewed. The dispensing point must be a licensed Saudi pharmacy; direct-to-home delivery without a licensed dispensing facility in the chain is not the model.

What is the safety profile we should expect?

The most common adverse events in the EMERGENT trials were gastrointestinal: nausea, dyspepsia, constipation, vomiting, abdominal pain, diarrhea, and gastroesophageal reflux. Most were mild or moderate and generally transient. Cardiovascular signals included hypertension and tachycardia. The drug avoids the EPS, tardive dyskinesia, weight gain, and prolactin signals associated with D2-blocking antipsychotics. Liver enzyme monitoring, blood pressure tracking, and

surveillance for symptoms of biliary disease or pancreatitis are part of routine care. Your psychiatrist will counsel your family on the full profile before starting.

What if my relative cannot tolerate the 125 mg / 30 mg target dose?

Patients who do not tolerate the 125 mg / 30 mg twice-daily target may step back to 100 mg / 20 mg twice daily and remain at that dose. Geriatric patients have a maximum recommended dose of 100 mg / 20 mg twice daily. Cobenfy is contraindicated in moderate to severe hepatic impairment and is not recommended in mild hepatic impairment.

Where Reserve Meds fits in Cobenfy cases

Reserve Meds is a US-based concierge coordinator. We do not replace your psychiatrist, do not replace SFDA, and do not replace your dispensing pharmacy. For a Cobenfy case in the Kingdom, we orchestrate the US specialty pharmacy procurement (Cobenfy moves through the BMS specialty pharmacy channel rather than open wholesale distribution), prepare the documentation kit your physician needs for the SFDA Personal Importation Program, coordinate the international shipment under ambient conditions with full customs documentation, and stay with the case through reorders under a single named coordinator. No prior Reserve Meds Cobenfy case experience is on file as of this page's review date, which is typical for a drug launched in late 2024; standard SFDA named-patient coordination applies, and the operational profile (small molecule, room temperature, oral, no REMS, no cold-chain, no reconstitution) is among the easier in the Reserve Meds matrix to coordinate. The clinical decisions remain with your treating psychiatrist. The regulatory authority remains SFDA. The dispensing remains with the licensed Saudi pharmacy.

Next step

If your family is exploring Cobenfy for an adult relative whose psychiatrist has documented prior-line failure or intolerance on D2 antagonists, the next step is to join the waitlist. We will confirm eligibility and case fit within 24 to 48 hours, send a documentation kit to your treating psychiatrist, and align with your institution's import pharmacy or with an SFDA-licensed specialty importer in Riyadh or Jeddah on the SFDA filing.

Reserved for you.

Related

- [Cobenfy drug overview](#)
- [Saudi Arabia country guide](#)
- [SFDA Personal Importation Program](#)
- [Cobenfy in the UAE](#)
- [Schizophrenia condition page](#)

Review & 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 >](#)

Last medically reviewed: 2026-05-12.