

[Skip to main content](#)

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

Rezdiffra access in Saudi Arabia through the SFDA Personal Importation Program

How Saudi adults with MASH and moderate-to-advanced liver fibrosis (F2 to F3) access Rezdiffra (resmetirom), the FDA-first MASH therapy, 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

Rezdiffra is the brand name for resmetirom, an oral once-daily small-molecule THR-beta selective agonist approved by the US FDA on 14 March 2024 (accelerated approval) for adults with noncirrhotic nonalcoholic steatohepatitis (NASH, also referred to as MASH under updated nomenclature) with moderate to advanced liver fibrosis, consistent with F2 to F3 stages. It is the first FDA-approved therapy for this indication and has not been registered with the SFDA for local commercial sale as of this page date. A Saudi adult with F2 or F3 fibrosis confirmed on non-invasive testing (NIT) can reach Rezdiffra lawfully through the SFDA Personal Importation Program (PIP), prescribed by a SCFHS-licensed hepatologist and dispensed by an SFDA-licensed hospital or specialty import pharmacy. Reserve Meds coordinates the US-side sourcing and the documentation kit your hepatologist needs to file the PIP application. Reserved for you.

Why Saudi patients need Rezdiffra through the named-patient pathway

MASH affects an estimated 1.5 to 6.5 percent of adults in the MENA region, driven by high regional prevalence of type 2 diabetes, central obesity, and metabolic syndrome. The treatment gap before Rezdiffra was real, and the launch of the first FDA-approved MASH therapy in March 2024 created a step change in regional hepatology demand. The structural access pattern in Saudi Arabia is the third of the three the country module describes: the drug is FDA-approved but the manufacturer (Madrigal Pharmaceuticals) has not sought SFDA registration, which is the most common pattern for recently launched specialty therapies where the local commercial case is still being built.

Saudi hepatology referral patterns at KFSH&RC, KAMC, and the major HMG facilities have been inquiring about Rezdiffra since the first quarter following FDA approval. Vision 2030's Health Sector Transformation Program names tertiary specialty care and digital diagnostic capacity expansion as priority verticals, and NIT-based diagnostic capability (transient elastography, MR elastography, validated blood-based panels) has expanded across Saudi tertiary centres. The result is a growing population of biopsy-spared, NIT-confirmed F2 to F3 patients whose hepatologist has identified Rezdiffra as the right next step and whose local supply chain does not yet hold it. The PIP framework was designed for exactly this situation: an FDA-approved medicine, no clinically equivalent locally registered alternative for the MASH histologic indication, and a serious progressive condition where the treating physician documents why this specific drug is appropriate.

The SFDA Personal Importation Program for Rezdiffra

The Saudi pathway for a KSA-licensed hepatologist to obtain Rezdiffra 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 (here, the FDA, with the European Commission having granted conditional marketing authorisation on 19 August 2025) and a clinically equivalent locally registered alternative is not suitable. Applications are filed through the dispensing institution's import pharmacy and increasingly routed through the SFDA Ghad digital platform.

For Rezdiffra specifically, the clinical-justification angle that anchors the application is the non-invasive testing diagnostic gate. The FDA-approved label does not require liver biopsy for diagnosis or treatment initiation. The PIP application is strongest when the hepatologist's letter sets out (1) the NIT-confirmed evidence of F2 or F3 fibrosis (FibroScan transient elastography kPa value, MR elastography result, or validated blood-based panel such as ELF, often combined with FAST or MAST composite scores), (2) the clinical picture supporting MASH (BMI, type 2 diabetes status, metabolic syndrome features, ALT/AST trajectory), (3) ruled-out alternative liver pathology (hepatitis B and C serology, autoimmune workup, iron studies, alpha-1 antitrypsin), (4) confirmed absence of decompensated cirrhosis (Child-Pugh A status if any cirrhosis is present, no ascites, no encephalopathy, no varices warranting prophylaxis), and (5) the proposed monitoring schedule for ALT, AST, alkaline phosphatase, and total bilirubin per the FDA label.

A complete PIP package typically includes:

- Clinical justification letter from the treating hepatologist (MASH diagnosis with NIT report, F2 or F3 staging, severity, prior lifestyle intervention history, why Rezdiffra, why a locally registered alternative is not suitable, requested dose and duration)
- Treating hepatologist SCFHS license verification valid for the requested treatment course
- NIT diagnostic report attached as a supporting document (FibroScan, MRE, or ELF panel with FAST or MAST composite where applicable)
- Patient identifier in SFDA-required format
- Product details: Rezdiffra film-coated tablets, 80 mg or 100 mg strength as appropriate to the patient's body weight, 30-tablet bottles, manufacturer Madrigal Pharmaceuticals Inc., country of origin USA, requested quantity per refill cycle and intended treatment duration
- 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 Rezdiffra is a recognised reference-authority drug with a well-documented FDA indication and a defined NIT-based diagnostic gate, established institutions like KFSH&RC, KAMC, and the major HMG hepatology services typically receive routine-track review once the diagnostic file is complete. First-import cases at smaller facilities or in less common patient profiles can extend to 6 to 10 weeks.

Where Rezdiffra gets dispensed in Saudi Arabia

Rezdiffra is a room-temperature stable oral tablet with no reconstitution and no cold chain. The capability that matters is hepatology service depth with NIT diagnostic capacity (transient elastography or MR elastography on site, or referral-based access), not infusion infrastructure or cell therapy capability. The Saudi institutions with this profile and with established import pharmacy workflow are:

- **King Faisal Specialist Hospital and Research Centre (KFSH&RC).** Tertiary and quaternary referral centre in Riyadh, Jeddah, and Madinah, with strong hepatology, liver transplant, and NIT diagnostic capability. In-house import pharmacy handles PIP filings as routine workflow.
- **King Abdulaziz Medical City (KAMC) and the MNGHA network.** Major tertiary care with strong hepatology and gastroenterology services in Riyadh and Jeddah.
- **King Saud University Medical City (KSUMC) and KSAU-HS affiliated centres.** Academic medical centres with hepatology research programs.
- **Dr. Sulaiman Al Habib Medical Group (HMG).** Largest private hospital network with multiple Riyadh, Jeddah, and Eastern Province facilities, hepatology depth, and routine PIP activity.

- **Saudi German Health, Dr. Soliman Fakeeh Hospital (Jeddah), and Dallah Hospital (Riyadh).** Private referral centres that handle import-pharmacy workflow and hepatology referrals.

For patients in the Eastern Province or other regions, NIT staging is typically obtained at the nearest tertiary centre, with prescribing and refill management routed through Riyadh or Jeddah hepatology service.

Real cost picture for Rezdiffra in Saudi Arabia

The US wholesale acquisition cost (WAC) for Rezdiffra is approximately USD 4,116 per 30-tablet bottle, with the same per-bottle price applying to the 80 mg and 100 mg adult strengths. At one bottle per month, annualised drug cost falls in a working range of approximately USD 47,400 to USD 49,000 (approximately SAR 178,000 to SAR 184,000 at the pegged rate of approximately 3.75 SAR to 1 USD) before any insurer or rebate adjustment. International logistics for an ambient-shipped oral tablet 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. US patient assistance through Rezdiffra Cares is restricted to US insured patients and does not extend to Saudi cases; the working assumption is full WAC plus coordination cost. Bupa Arabia, Tawuniya, and MedGulf handle named-patient imports case by case; in MASH there is no public-sector reimbursement framework as of this page date, and cash-pay is the default operating posture.

Typical timeline for Rezdiffra in Saudi Arabia

Rezdiffra 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 5 to 8 weeks: 10 to 21 business days for routine SFDA review at an established tertiary centre, 5 to 7 days for US-side specialty pharmacy procurement of the 30-tablet bottle, and 3 to 5 days for ambient air freight and Saudi customs clearance. Repeat refill cycles for an established patient compress to 3 to 4 weeks because the PIP dossier, the NIT diagnostic baseline, the importer relationship, and the US-side procurement path are already in place. Monthly cadence (one 30-tablet bottle per month) supports a quarterly or semi-annual shipment rhythm if the hepatologist confirms supply alignment with monitoring visits.

What your physician needs to provide

The treating hepatologist's clinical justification letter is the cornerstone of the SFDA PIP package. For Rezdiffra specifically, the letter typically addresses:

- **Mechanism and FDA indication.** Resmetirom is a liver-directed thyroid hormone receptor-beta selective agonist intended to reduce hepatic triglyceride accumulation, hepatocellular injury, and downstream fibrogenesis. FDA-approved 14 March 2024 (accelerated approval) for adults with noncirrhotic MASH and F2 to F3 fibrosis, used in combination with diet and exercise.
- **NIT diagnostic gate.** Documentation of F2 to F3 fibrosis via transient elastography (FibroScan kPa value), MR elastography, or validated blood-based panel (ELF), typically combined with FAST or MAST composite scoring. Liver biopsy is not required per the FDA-approved label.
- **Ruled-out alternative pathology.** Hepatitis B and C serology, autoimmune liver disease workup, iron studies, alpha-1 antitrypsin, alcohol history.
- **Decompensation status.** Confirmation of noncirrhotic status or, where compensated cirrhosis is suspected, Child-Pugh A with no ascites, encephalopathy, or variceal bleeding history. Use is not approved in decompensated cirrhosis (Child-Pugh B or C).

- **Dosing plan.** 80 mg once daily for body weight under 100 kg; 100 mg once daily for body weight 100 kg or greater. Once daily with or without food, tablets swallowed whole.
- **Monitoring plan.** Baseline and periodic monitoring of ALT, AST, alkaline phosphatase, and total bilirubin per the FDA label, with defined thresholds for dose interruption. Concomitant medication review for CYP2C8 inhibitors and statin co-administration adjustments.
- **Physician license.** Active SCFHS registration in hepatology, gastroenterology, or internal medicine with hepatology focus, valid for the requested treatment window.

Common questions about Rezdifra in Saudi Arabia

Do I need a liver biopsy to start Rezdifra?

No. The FDA-approved label does not require liver biopsy for diagnosis or treatment initiation. F2 to F3 fibrosis can be supported by non-invasive testing such as FibroScan transient elastography, MR elastography, or validated blood-based panels like ELF, often combined with FAST or MAST composite scores. This non-invasive diagnostic gate is the substantive practical change from the biopsy-based enrollment criteria of the MAESTRO-NASH pivotal trial.

Will Bupa Arabia, Tawuniya, or MedGulf cover this?

Each insurer assesses named-patient MASH imports case by case. There is no public-sector reimbursement framework for Rezdifra in KSA as of this page date, and most private plans treat MASH therapy as an evolving formulary area. We supply the documentation set that lets your insurer assess; the claim sits with you or your hospital. Cash-pay is the default operating posture.

What is the safety profile?

The most commonly reported adverse events in MAESTRO-NASH were diarrhoea and nausea, generally early in therapy. The FDA label includes warnings around drug-induced liver injury, hepatic decompensation in unrecognised cirrhosis, and gallbladder-related adverse reactions. Serious adverse event rates were comparable across the 80 mg, 100 mg, and placebo arms in the pivotal trial. The prescribing hepatologist owns the safety assessment.

How is treatment duration set?

Rezdifra is intended as chronic ongoing treatment. There is no defined stop date in the FDA label. Continuation is based on the treating hepatologist's longitudinal assessment of tolerability, monitoring labs, and follow-up NIT testing. Treatment may be paused or discontinued if predefined ALT, AST, or bilirubin thresholds are crossed, or if the patient progresses to decompensated cirrhosis.

Is GLP-1 a substitute?

GLP-1 receptor agonists such as semaglutide are studied for MASH and may be used by clinicians for comorbid metabolic disease, but they are not FDA-approved for the MASH histologic indication. As of this page date, Rezdifra is the only FDA-approved therapy for noncirrhotic MASH with F2 to F3 fibrosis. Reserve Meds does not endorse off-label substitution.

Does monitoring change if I'm on a statin?

Yes. The FDA label specifies statin co-administration dose adjustments and a baseline lipid panel with periodic monitoring during treatment. Your hepatologist will coordinate the statin review and adjust dosing as the label directs. Strong CYP2C8 inhibitors are a separate flag.

Where Reserve Meds fits in Rezdiffra cases

Reserve Meds is a US-based concierge coordinator. We do not replace your hepatologist, SFDA, or your dispensing pharmacy. For Rezdiffra specifically, we orchestrate the US-side sourcing through a DSCSA-compliant specialty pharmacy that holds the 30-tablet bottle inventory, prepare the documentation kit your Saudi hepatologist needs to file the PIP application (with the NIT diagnostic-gate language, FDA-label dosing plan, and monitoring schedule templates pre-built), align the ambient air-freight shipment plan with the Saudi importer, and assign a single named coordinator who carries you through the first cycle and the monthly refill cadence. No prior Reserve Meds closed-case experience for Rezdiffra as of this page date; standard NPP coordination applies. The room-temperature storage profile makes Rezdiffra one of the logistically simpler cases on our matrix.

Next step

If you have an NIT-confirmed MASH diagnosis at F2 or F3 fibrosis and your Saudi hepatologist has identified Rezdiffra 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 hepatologist.

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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