Herceptin

Saudi Arabia · access guide

How to access Herceptin from Saudi Arabia, the named-patient import pathway, 2026

By Reserve Meds, Clinical and regulatory team. Last reviewed 2026-05-13.

A Saudi Arabiai patient with HER2-overexpressing breast cancer in the adjuvant and metastatic settings, and HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma may receive a prescription for Herceptin (trastuzumab) from their treating oncologist. Herceptin is FDA-approved in the United States and manufactured by Genentech (Roche). It is a humanised HER2-directed monoclonal antibody administered by intravenous infusion. Local availability of Herceptin in Saudi Arabia can be inconsistent: the drug may not be on every specialty pharmacy's standing formulary, the specific indication may not match what is locally registered, or the strength required may be back-ordered. When that happens, a named-patient import pathway through SFDA remains a legitimate route for the patient whose physician has already prescribed the drug.

This guide explains the pathway, the documentation your physician needs, typical costs and indicative timing, and where Reserve Meds fits in.

The clinical situation

Herceptin is a humanised HER2-directed monoclonal antibody. Mechanism: a humanised IgG1 monoclonal antibody that binds the extracellular domain of HER2 and inhibits downstream signaling. Dosing: loading and maintenance dosing by intravenous infusion every 1 or 3 weeks per FDA labeling; subcutaneous Herceptin Hylecta is an alternative. Baseline workup per FDA labeling includes baseline left ventricular ejection fraction by echocardiogram or MUGA, complete blood count, and HER2 testing confirmation (IHC 3+ or ISH amplified). The FDA boxed warning covers cardiomyopathy, infusion reactions, pulmonary toxicity, and embryo-fetal toxicity. Other important warnings include cardiomyopathy, infusion reactions, pulmonary toxicity, and embryo-fetal toxicity. Your oncologist will discuss the risk-benefit profile and schedule monitoring before initiating therapy.

Is Herceptin legally importable into Saudi Arabia?

Yes, through the Saudi Arabia Saudi Food and Drug Authority (SFDA) named-patient and personal-use import framework, coordinated with the treating facility's pharmacy. The Saudi Arabia has an established pathway for specialty medicines approved by reference authorities (US FDA, EMA, MHRA) but not stocked or registered for the specific indication locally.

The SFDA named-patient route allows a Saudi Arabiai-licensed physician to request import of a medicine when: (a) the medicine is approved by a recognised reference authority, (b) no clinically equivalent locally registered alternative is suitable for the patient's indication and history, (c) the treating physician takes clinical responsibility for use, and (d) chain of custody is documented from the US source to the administering facility. Applications are typically filed through the dispensing institution's import pharmacy on the physician's behalf, with approval issued on a per-patient, per-cycle quantity basis.

How the pathway works, step by step

1. **Consultation with your treating oncologist.** The prescribing decision is clinical. Your oncologist documents the indication, prior therapies where relevant, and rationale for Herceptin.
2. **Baseline screening.** Baseline left ventricular ejection fraction by echocardiogram or MUGA, complete blood count, and HER2 testing confirmation (IHC 3+ or ISH amplified) are confirmed and documented.
3. **SFDA named-patient application.** Your oncologist or the facility's import pharmacy files the application with clinical rationale, patient reference, product strength, quantity requested, and chain-of-custody plan.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure product from Genentech (Roche)'s authorised distribution under DSCSA chain-of-custody.
5. **Cold-chain shipment.** Herceptin requires refrigerated transport at 2 to 8 degrees Celsius. Shipments include temperature-monitored packaging with continuous loggers and tamper-evident seals.
6. **Arrival and first dose.** The dispensing pharmacy releases product against the physician's prescription, and your oncologist initiates therapy.

What documentation your physician needs

Your physician will typically need to provide:

- A clinical rationale letter confirming diagnosis, prior therapies where relevant, and Herceptin as the indicated next step
- Verification of their Saudi Arabiai medical licence
- A patient identifier, anonymised reference where privacy is preferred
- Documented pre-treatment screening consistent with FDA labeling (see above)
- The planned dosing regimen (loading and maintenance dosing by intravenous infusion every 1 or 3 weeks per FDA labeling; subcutaneous Herceptin Hylecta is an alternative)
- A monitoring plan covering HER2 confirmation, LVEF baseline, and biosimilar-versus-originator preference note

Reserve Meds provides a physician documentation kit tailored for HER2-directed monoclonal antibody therapies, including the templates SFDA reviewers commonly request.

Typical costs and indicative timing

Reserve Meds gives you a drug-only reference range plus a transparent delivered quote at intake. As an illustrative composite case, the US cash-pay reference range for a single every-3-week cycle (weight-dependent; biosimilars often lower) of Herceptin sits in an indicative 2026 band of approximately USD 4,000 to 6,500. International logistics, SFDA documentation handling, cold-chain shipping, and concierge coordination add incremental cost. The delivered quote we issue at intake shows each line separately.

Indicative timing for first dose after cohort intake opens is approximately 2 to 5 weeks from the moment a complete application is submitted, assuming the documentation package is clean on first pass. Refills ship on a rolling cadence aligned to the dosing schedule.

Service availability is limited to our first cohort. All timelines are indicative, not guarantees.

Where Reserve Meds fits in

Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Herceptin specifically, we provide:

- **Sourcing.** Through our US-licensed specialty wholesale partner, operating under DSCSA chain-of-custody from manufacturer to export.
- **Documentation.** Regulatory package tailored for your physician and for SFDA review, including HER2-directed monoclonal antibody class templates.
- **Cold-chain logistics.** Temperature-monitored, internationally tracked shipment to your named dispensing facility with continuous temperature loggers.
- **Concierge case lead.** A named point of contact for your family and your physician across the full case arc.

We are a coordinator. We are not the prescriber, not a pharmacy, and not a dispensing facility. All clinical decisions remain with your treating oncologist, and dispensing sits with the licensed Saudi Arabiai pharmacy of record. Reserve Meds operates on cash-pay only and does not bill insurance.

Frequently asked

Is this legal in Saudi Arabia? Yes, when executed through the SFDA named-patient and personal-use framework with appropriate documentation, clinical rationale, and a licensed dispensing facility. The pathway is routinely used across oncology, rare disease, and immunology at Saudi Arabiai tertiary centers.

What about the boxed warning? The FDA boxed warning on Herceptin covers cardiomyopathy, infusion reactions, pulmonary toxicity, and embryo-fetal toxicity. Your oncologist performs the risk-benefit assessment, schedules monitoring, and counsels the patient per labeling. Reserve Meds does not make that clinical judgement, your physician does.

Will my private health insurance cover this? Cash-pay is the default posture. Some Saudi Arabiai private insurers reimburse named-patient imports on a case-by-case basis. We supply documentation for your submission but do not process insurance claims.

How does cold-chain affect timing? Herceptin ships refrigerated. We use validated packaging with continuous temperature monitoring, and arrival temperature data is logged on every shipment.

What if my physician has not filed a named-patient request before? Named-patient import is an institutional process most major Saudi Arabiai tertiary centers (King Hamad University Hospital, Salmaniya Medical Complex, and the Saudi Arabia Oncology Center) have encountered. Our documentation kit is written for first-time applicants and tracks what SFDA reviewers commonly ask for.

Reserve Meds's role

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

Reserve Meds

reserved for you.

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