Tavalisse access in the United Arab Emirates: the EDE named-patient pathway

How UAE adults with chronic immune thrombocytopenia pursue fostamatinib, the oral spleen tyrosine kinase (SYK) inhibitor, when corticosteroids, intravenous immunoglobulin, splenectomy, rituximab, and thrombopoietin receptor agonists have not delivered durable platelet response.

Last reviewed 2026-05-12 by the Reserve Meds clinical and regulatory team. This page combines the UAE country research module with the Tavalisse drug module to describe the path families actually walk.

Quick orientation

Tavalisse (fostamatinib disodium hexahydrate) is an oral spleen tyrosine kinase (SYK) inhibitor developed by Rigel Pharmaceuticals. The US Food and Drug Administration approved Tavalisse in April 2018 for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. The standard starting dose is 100 mg orally twice daily, increased to 150 mg twice daily after 4 weeks if platelet response is insufficient. The SYK mechanism distinguishes fostamatinib from the thrombopoietin receptor agonists (eltrombopag, romiplostim, avatrombopag), which act on platelet production rather than on Fc-receptor-mediated platelet destruction. Reserved for you.

Why UAE patients need Tavalisse via a named-patient pathway

Chronic immune thrombocytopenia is a rare-but-not-orphan hematology condition with a UAE prevalence consistent with regional adult haematology cohorts. The first-line treatment is corticosteroids, with intravenous immunoglobulin for acute bleeding. Second-line options include splenectomy, rituximab, and the thrombopoietin receptor agonists eltrombopag (Promacta), romiplostim (Nplate), and avatrombopag (Doptelet). The locally available landscape in the UAE includes eltrombopag and romiplostim at most major hematology centres, with established MoHAP registration.

The case for Tavalisse specifically is built when the patient has not achieved durable platelet response on a thrombopoietin receptor agonist, when splenectomy has been declined or has not delivered remission, or when the treating haematologist wants the SYK mechanism specifically for a patient whose ITP appears Fc-receptor-mediated destruction-dominant. Tavalisse is not consistently held in UAE federal stock at the level of eltrombopag. The EDE named-patient pathway is the established route.

The EDE / MoHAP named-patient pathway applied to Tavalisse

The federal pathway for a UAE-licensed physician to obtain a medicine that is not registered or not stocked locally is the unregistered-medicine import permit, administered through the Emirates Drug Establishment (EDE) at ede.gov.ae. The EDE took over 44 core services from MoHAP under Federal Decree-Law No. 38 of 2024. The framework allows hospitals and licensed pharmaceutical establishments to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority such as the US FDA and a locally registered alternative is not suitable.

For Tavalisse, the clinical justification packet is structured around the chronic ITP treatment trail. The treating haematologist documents the diagnosis (chronic immune thrombocytopenia, by ITP duration of more than 12 months), the platelet count trajectory, the bleeding history, the prior therapy trail (corticosteroid history with duration and response, intravenous immunoglobulin for acute episodes, splenectomy status, rituximab exposure where applicable, thrombopoietin receptor agonist exposure with eltrombopag, romiplostim, or avatrombopag including response and reason for switching), and the rationale for switching to or adding the SYK inhibitor mechanism.

A complete EDE application for Tavalisse typically includes the haematologist's clinical justification letter, the treating physician's MoHAP, DHA, DoH, or Sharjah Health Authority licence verification, an anonymised patient identifier, full product details (Tavalisse 100 mg or 150 mg oral tablets), the destination dispensing pharmacy name with licence number and pharmacy in charge, and the patient informed consent. Approval timelines for routine cases are 5 to 15 business days.

Where Tavalisse gets dispensed in the UAE

Tavalisse is an oral tablet with standard ambient storage at 20 to 25 degrees Celsius. The dispensing site is the outpatient pharmacy attached to the treating haematology service. The most natural dispensing sites are the haematology services at Cleveland Clinic Abu Dhabi, Sheikh Khalifa Medical City, American Hospital Dubai, Mediclinic City Hospital in

Dubai Healthcare City, NMC Royal Hospital, Tawam Hospital, and the specialised haematology departments within the SEHA network.

Real cost picture for Tavalisse in the UAE

The US wholesale acquisition cost for Tavalisse is approximately USD 12,000 to 15,000 per month at the standard 100 mg twice-daily or 150 mg twice-daily dose, translating to approximately AED 44,000 to 55,000 monthly at the 3.67 peg. The figure is the drug acquisition cost only.

All-in delivered cost stacks the drug acquisition, ambient international logistics (USD 400 to 700 per shipment), EDE handling and customs (USD 300 to 600 per case), the dispensing pharmacy fee, and the Reserve Meds concierge coordination fee. Insurance in the UAE handles chronic ITP biologics and small-molecule therapies case by case. Pre-authorisation is the norm. Thiqa, administered by Daman, has the broadest specialty coverage for UAE nationals in Abu Dhabi. We do not promise coverage.

Typical timeline for Tavalisse in the UAE

The EDE permit processes in 5 to 15 business days for a routine submission with a clear chronic ITP rationale and a documented treatment trail. International logistics for an ambient-shipped oral medication adds 3 to 7 business days. Customs clearance is typically 1 to 3 business days. A patient who completes the documentation in week one typically receives the first prescription in week three to week five. Initial response assessment is at week 4 (with dose escalation to 150 mg twice daily if needed); the haematologist evaluates durable platelet response over the first 12 weeks.

What your physician needs to provide

The clinical justification letter for a Tavalisse EDE submission is tightly scoped to the chronic ITP treatment history. The treating haematologist's letter typically addresses the diagnosis (chronic ITP, duration confirmed), the platelet count trajectory, the bleeding history (mucosal bleeding, intracranial haemorrhage concern, surgical or dental procedure requirements), the prior therapy trail with response and reason for switching at each step, and the rationale for adding the SYK inhibitor mechanism. The letter references the Rigel US label and the proposed starting dose with the week-4 escalation criteria.

The treating physician's licence must be in active standing in the emirate of the dispensing facility (MoHAP for the Northern Emirates, DHA for Dubai, DoH for Abu Dhabi and Al Ain, Sharjah Health Authority for Sharjah). The patient signs informed consent reflecting the adverse-event profile (diarrhoea, hypertension, hepatotoxicity, neutropenia).

Pharmacovigilance considerations

The adverse-event profile of fostamatinib is led by diarrhoea, hypertension, hepatotoxicity, and neutropenia. The US label specifies baseline blood pressure measurement with monthly monitoring and dose adjustment for hypertension that develops on therapy, baseline liver function tests with monthly monitoring for the first three months, and baseline absolute neutrophil count with periodic monitoring. Fostamatinib is metabolised primarily by CYP3A4 and the US label provides specific guidance on concurrent strong CYP3A4 inhibitors and inducers. Adverse events identified by the treating team route to Rigel's safety reporting channel and to the EDE post-market surveillance address.

Common questions about Tavalisse in the UAE

Why Tavalisse rather than another thrombopoietin receptor agonist? The thrombopoietin receptor agonists (eltrombopag, romiplostim, avatrombopag) and the SYK inhibitor fostamatinib act on different parts of the ITP pathophysiology. TPO-RAs stimulate platelet production; fostamatinib reduces Fc-receptor-mediated platelet destruction. For a patient who has not had durable response on a TPO-RA, the SYK mechanism is the alternative. The clinical choice rests with the treating haematologist.

Will Daman, Thiqa, or my private insurer cover this? Each insurer assesses chronic ITP therapies case by case. Pre-authorisation is the norm. Thiqa has the broadest specialty coverage in Abu Dhabi. We do not promise coverage.

Is Tavalisse a controlled substance? No. Tavalisse is not a DEA scheduled substance.

How long until I know if Tavalisse is working? The US label specifies a week-4 evaluation point with escalation from 100 mg twice daily to 150 mg twice daily if platelet response is insufficient. Durable response assessment is over the first 12 weeks of therapy.

What patients ask when they first call

"How does the case actually start?" The patient or the treating haematologist contacts Reserve Meds through the waitlist form. Within 24 to 48 hours, a coordinator confirms eligibility, sends the documentation kit to the physician, and outlines the EDE submission sequence. No payment is taken at this stage.

"What is the day-to-day adverse-event profile?" Diarrhoea is the most common adverse event on fostamatinib and is typically mild to moderate. Hypertension that develops on therapy is managed with antihypertensive initiation or escalation per the US label. Liver function abnormalities are typically asymptomatic and reverse with dose reduction. The treating haematologist coordinates the monitoring schedule.

"What if my platelet count does not respond by week 4?" The US label specifies dose escalation from 100 mg twice daily to 150 mg twice daily at week 4 if the platelet count is less than 50,000/microL. Patients who do not respond by week 12 on the maximum dose are typically discontinued, and the treating haematologist re-evaluates the regimen.

"Can fostamatinib be combined with other ITP therapies?" The US label position is monotherapy for chronic ITP. In practice, the treating haematologist may layer ongoing corticosteroid taper or other immunomodulators with fostamatinib based on the individual case. Combinations are not the FDA-approved use.

Where Reserve Meds fits in Tavalisse cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating haematologist, the EDE, or the dispensing pharmacy. For a Tavalisse case, our work is the regulatory documentation assembly, the US-side procurement coordination with the Rigel specialty distributor, the logistics, the customs handoff, and a single named coordinator for the patient through onboarding and the recurring monthly supply. Reserved for you.

Documentation kit for the treating haematologist

The documentation kit Reserve Meds sends the treating haematologist after a waitlist confirmation contains the EDE clinical-justification letter template tailored to the SYK inhibitor mechanism in chronic ITP, the platelet-count trajectory capture sheet, the prior corticosteroid, IVIg, splenectomy, rituximab, and TPO-RA exposure capture sheet, the dose proposal with week-4 escalation guidance, the baseline blood pressure, liver function, and absolute neutrophil count capture sheet, the monthly monitoring template, the patient informed consent template covering the adverse-event profile, and the dispensing pharmacy intake checklist for the recurring monthly supply. The kit is built so the haematology clinic spends minimum time on form work and maximum time on the patient conversation and the response assessment that anchor the chronic-ITP regimen.

Next step

If a treating haematologist in the UAE is weighing Tavalisse for an adult patient with chronic ITP, the waitlist is the first step. We respond within 24 to 48 hours with an eligibility confirmation and a documentation kit for the physician.

Reserved for you.

Related

- Tavalisse clinical resource
- Immune thrombocytopenia
- United Arab Emirates country page
- Named-patient pathway overview

Sources

1. FDA approval, Tavalisse (fostamatinib disodium hexahydrate), Rigel Pharmaceuticals, approval April 2018 for chronic immune thrombocytopenia in adults.
2. UAE Federal Decree-Law No. 38 of 2024 and the Emirates Drug Establishment portal at ede.gov.ae.
3. Rigel Pharmaceuticals US prescribing information for Tavalisse (fostamatinib), 100 mg and 150 mg oral tablets, 100 mg twice daily with escalation to 150 mg twice daily.