

## Dificid

Saudi Arabia · access guide

# How to access Dificid for Clostridioides difficile infection (CDI) from Saudi Arabia: 2026 pathway via KFSHRC and Saudi infectious diseases and gastroenterology services

By Reserve Meds clinical & regulatory team. Last reviewed 2026-05-20.

Saudi Arabia has the deepest adult and paediatric infectious diseases and gastroenterology bench in the wider region. King Faisal Specialist Hospital and Research Centre (KFSHRC) Riyadh and Jeddah, King Abdulaziz Medical City (KAMC) Riyadh, King Fahd Medical City (KFMC) Riyadh, Prince Sultan Military Medical City Riyadh, King Khaled University Hospital, Dr Sulaiman Al Habib network, Saudi German Hospital, Mouwasat, and the Aramco medical services in the Eastern Province all run ID and GI consultation services that routinely manage Clostridioides difficile infection (CDI): the first hospital-acquired episode after broad-spectrum antibiotic exposure, the high-recurrence-risk patient on a transplant or oncology pathway who cannot stop the precipitating antibiotic, the first recurrence that triggers the recurrence-prevention conversation, and the multi-recurrence patient where the next conversation is between fidaxomicin extended-pulse and faecal microbiota transplant (FMT). KFSHRC Riyadh in particular runs the deepest regional FMT programme and the deepest transplant-population CDI experience. Dificid (fidaxomicin, Merck; Dificlir in EU and UK markets) is the first-in-class macrocyclic antibiotic with narrow C. difficile-selective spectrum and minimal systemic absorption that delivers approximately 14% recurrence at day 28 versus approximately 25% for oral vancomycin in the pivotal trials. For a KSA-resident adult or paediatric patient (6 months or older) with confirmed CDI where the prescribing physician has decided the operational priority is recurrence prevention, the question is no longer whether fidaxomicin is reachable: it is how the 10-day course is sourced, dispensed, and paid for, what the antibiotic stewardship committee at the prescribing centre needs to see in the case file, and how the patient completes the course at home after discharge.

This page explains how the pathway works in 2026 for a Saudi-resident patient: who qualifies (adult or paediatric 6 months and older), where the prescribing ID or GI conversation happens, how Dificid is sourced and dispensed (formulary stock at major KSA tertiary centres where available, named-patient European-import via Dificlir ex-EU where not), how the 10-day course is delivered (oral tablet or oral suspension, no IV access required), what the cost band looks like in SAR, what to monitor (clinical response at day 3 to 5 and day 10, recurrence at day 28), and how the antibiotic stewardship conversation runs in parallel with the prescribing conversation. It is concierge documentation written for a family already in conversation with a treating ID or GI specialist who wants the operational reality laid out plainly.

## Why Dificid, and why now

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Dificid is fidaxomicin, a first-in-class macrocyclic antibiotic with a narrow Gram-positive spectrum that is highly selective for *C. difficile*. The mechanism is inhibition of bacterial RNA polymerase via binding to the sigma factor switch region, which is mechanistically distinct from vancomycin (cell-wall biosynthesis inhibition), metronidazole (DNA strand breakage), or any other antibiotic class in current use. The bactericidal action is local to the colonic lumen because fidaxomicin is minimally absorbed systemically after oral administration. The clinical consequence is a narrow effect on the colonic microbiota beyond *C. difficile*, with relative preservation of microbiome diversity compared with the broader disruption seen with oral vancomycin. This microbiome-sparing pharmacology is believed to be the mechanism behind the lower recurrence rate.

The FDA approved Dificid for CDI in adults in May 2011, then expanded the label to paediatric patients 6 months and older in January 2020 and added the extended-pulsed dosing regimen in February 2021. The EMA approved Dificlir in December 2011. The IDSA / SHEA 2021 guidelines moved fidaxomicin above oral vancomycin to first-line for initial CDI in adults on the strength of the lower recurrence rate evidence. Saudi SFDA registration status is verified at intake; where Dificid is on hospital formulary at KFSHRC, KAMC, KFMC, Prince Sultan Military Medical City, or another major KSA tertiary centre, in-country dispensing applies, and where it is not in formulary or stock is unavailable, named-patient European import via Dificlir ex-EU is the supply route.

For a KSA patient with confirmed CDI where the prescribing ID or GI specialist has decided the operational priority is recurrence prevention, Dificid is the macrocyclic antibiotic that the conversation centres on. The clinical decision about Dificid versus oral vancomycin versus, in resource-limited contexts, metronidazole is the prescribing specialist's. This page is the operational layer underneath that decision.

Reserve Meds does not promote one antibiotic over another. The page describes the Dificid pathway because Dificid is the drug the patient has been prescribed or has asked about.

## What Dificid is, in plain language

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Dificid is an oral drug. The adult patient takes one 200 mg tablet by mouth twice daily for 10 days. Paediatric patients 6 months and older who can swallow tablets and meet weight criteria take the same 200 mg tablet twice daily; younger or smaller paediatric patients take the oral suspension (40 mg/mL) with weight-based dosing per the prescribing paediatric specialist. There is no IV access, no infusion appointment, no home injection, and no infusion-pump device.

The 10-day course is taken at home in most cases after the initial inpatient diagnosis and the first one or two doses delivered on the ward. Standard supportive care (hydration, contact precautions in the inpatient setting, discontinuation of the precipitating antibiotic where possible) continues independently. No serum drug-concentration monitoring is required. No renal or hepatic dose adjustment is required.

Dificid is not interchangeable with oral vancomycin; they belong to different drug classes with different recurrence-rate profiles. The ID or GI specialist chooses one or the other based on the recurrence-risk assessment, the cost conversation, and stewardship approval.

## **Eligibility at a Saudi infectious diseases or gastroenterology clinic**

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For KSA-resident patients, the ID and GI services apply the IDSA / SHEA criteria with local operational adaptation:

1. Confirmed CDI diagnosis: stool toxin enzyme immunoassay, PCR for toxigenic *C. difficile*, GDH plus toxin EIA, or the multi-step algorithm per the local microbiology pathway. Three or more unformed stools per 24 hours plus laboratory confirmation. Asymptomatic carriage is not an indication.
2. Adult (18 or older) or paediatric (6 months or older). Paediatric patients under 6 months route to paediatric infectious diseases for off-label management.
3. Severity assessment. White blood count, serum creatinine, serum albumin, lactate. Severe CDI or fulminant CDI (hypotension, ileus, toxic megacolon) requires hospital-level care with broader management.
4. Recurrence risk assessment. Age over 65, immunocompromise, transplant population, concurrent broad-spectrum antibiotic that cannot be stopped, severe disease, prior CDI episode. The higher the recurrence risk, the stronger the case for fidaxomicin over vancomycin.
5. Renal and hepatic function. Not for dose adjustment, but as a general workup baseline.
6. Pregnancy and breastfeeding review. Limited human data; use only if benefit clearly outweighs risk. Breastfeeding is generally permitted given minimal systemic absorption.
7. Concurrent medication review. Minimal drug-drug interactions because of low systemic exposure.
8. Allergy review. Macrolide cross-reactivity is not established. Prior fidaxomicin hypersensitivity is a contraindication.
9. Concurrent antibiotic management. The precipitating antibiotic is discontinued or de-escalated where clinically possible.
10. Antibiotic stewardship sign-off. The prescribing centre's stewardship committee or designated infectious diseases pharmacist reviews the case before fidaxomicin is dispensed.

A KSA patient should arrive at the Dificid conversation with the most recent clinical documentation: stool toxin or PCR result, current and recent antibiotic history, severity markers, recurrence-risk profile, current medication list, allergy history, renal and hepatic baseline labs, and the insurance or state-funded coverage paperwork that the prescribing office initiates.

## **The Saudi prescribing and supply picture, plainly**

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Dificid Saudi SFDA registration status is verified at intake. Commercial registration of fidaxomicin in KSA exists at the tertiary-hospital-formulary level at the major centres (KFSHRC Riyadh and Jeddah, KAMC Riyadh, KFMC, Prince Sultan Military Medical City, King Khaled University Hospital, Dr Sulaiman Al Habib, Saudi German Hospital) on a stewardship-gated basis; at smaller hospitals and community pharmacies the drug is generally not stocked and named-patient European import via Dificlir ex-EU coordinated through licensed regional specialty distributors and the prescribing centre's hospital pharmacy is the operational supply route. The pathway is:

1. Prescribing physician: a board-certified KSA infectious diseases specialist or gastroenterologist. KFSHRC Riyadh runs the deepest ID, GI, and FMT programme in the country and the deepest transplant-population CDI experience. KFSHRC Jeddah, KAMC Riyadh, KFMC, Prince Sultan Military Medical City, King Khaled University Hospital, and the Aramco medical service in the Eastern Province are the principal alternatives. The private sector ID and GI services at Dr Sulaiman Al Habib, Saudi German Hospital, and Mouwasat handle CDI for the commercially insured population. Paediatric CDI routes to paediatric infectious diseases or paediatric GI at KFSHRC, KAMC, or KFMC paediatric services. 2. Pharmacy dispensing and supply: hospital pharmacy at the prescribing centre. Where in-formulary stock exists, in-country dispensing applies. Where stock is unavailable or the centre does not stock fidaxomicin, named-patient European import via licensed regional distributors covers the case. Lead time from order to dispensing is typically 5 to 10 business days for named-patient supply. 3. Antibiotic stewardship sign-off. The prescribing centre's stewardship committee reviews the case file before fidaxomicin dispensing. Documentation required: confirmed CDI diagnosis, severity assessment, recurrence-risk profile, prior CDI history, current and recent antibiotic exposure, and the prescribing physician's rationale for fidaxomicin over vancomycin. 4. Insurance pre-authorisation: for Saudi nationals, MoH and state-funded hospital coverage extends to ID-prescribed antimicrobial therapy at KFSHRC, KAMC, KFMC, and military medical centres including fidaxomicin where the recurrence-risk rationale is documented. For expat residents, commercial insurance pre-authorisation is the path; the framing that lands with payers is the total-cost-of-care comparison: a 10-day course of fidaxomicin versus a 10-day course of vancomycin plus the probabilistic cost of a recurrence (re-hospitalisation, repeat course, possible FMT). [VERIFY: current Saudi SFDA registration status at intake.] 5. Ongoing monitoring: clinical assessment at day 3 to 5 (reduction in stool frequency, resolution of fever, improvement in abdominal pain), day 10 (clinical cure), and day 28 (recurrence assessment). Repeat stool testing is not required for cure assessment in the absence of recurrent symptoms.

## **Cost band and insurance positioning**

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US list price for a 10-day adult course of Dificid (20 tablets of 200 mg) sits at approximately USD 3,000 to 4,500 at WAC depending on package and contract.

At 2026 indicative cross rates, the SAR-equivalent course cost band for cash-pay is approximately SAR 13,100 to 24,400 per 10-day course inclusive of named-patient supply where applicable and dispensing fees. Where the drug is on hospital formulary at a KSA tertiary centre and the patient is a Saudi national, out-of-pocket cost may be substantially lower or zero. The cost case versus a 10-day course of oral vancomycin (which can run SAR 200 to 600 for the generic course) is the conversation that gates fidaxomicin selection in cost-sensitive contexts. The total-cost-of-care argument (recurrence prevention, avoided re-hospitalisation, avoided second course, possible avoided FMT) is the framing that lands with payers.

For Saudi nationals at KFSHRC, KAMC, KFMC, or military medical centres, the state-funded pathway is the dominant pre-authorisation route. For expat residents, the commercial insurance pre-authorisation conversation needs to start during the inpatient admission, not at discharge.

## What to expect on Dificid, from day one forward

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Day 1: the first dose is typically given on the inpatient ward at the prescribing centre after CDI diagnosis is confirmed and stewardship approval has been documented. The patient takes one 200 mg tablet by mouth (or the weight-based oral suspension dose for paediatric patients) twice daily. The precipitating antibiotic is discontinued where it can be stopped. Hydration is maintained. Contact precautions remain in place in the inpatient setting.

Day 3 to 5: clinical assessment by the prescribing ID or GI office. The expected finding is a reduction in stool frequency, resolution of fever if present, and improvement in abdominal pain. If clinical response is inadequate at this point, the prescribing specialist reassesses.

Day 10: completion of the standard course. Clinical cure is documented. The patient is counselled on recurrence warning signs.

Day 28: recurrence assessment. The patient or family contacts the prescribing office if watery diarrhea returns within 4 to 8 weeks. Repeat stool testing is not done routinely in the absence of symptoms.

If recurrence occurs, the conversation reopens: a first recurrence after a fidaxomicin initial course can be managed with extended-pulsed fidaxomicin (200 mg BID days 1 through 5, then 200 mg every other day on days 7 through 25) or with faecal microbiota transplant (FMT) at KFSHRC Riyadh, which runs the deepest regional FMT programme.

## Religious and ethical considerations

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Fidaxomicin is a fully synthetic fermentation-derived macrocyclic antibiotic with no human or animal source material; halal-compatible and kosher-compatible by general consensus on fermentation-derived antibiotics. The oral route has no ritual implications. Ramadan timing for a twice-daily oral dose is operationally simple (before suhoor and after iftar) although the underlying CDI illness with diarrhea typically exempts the patient from fasting on medical grounds in most jurisprudential frameworks; the prescribing physician and the family religious adviser address this case by case. For paediatric patients, the parental consent process at the prescribing KSA centre includes the standard discussion of off-formulary cost (where applicable) and the rationale for fidaxomicin over vancomycin in the recurrence-risk context.

## When Dificid is the wrong drug

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For a KSA patient with fulminant CDI (hypotension, ileus, toxic megacolon, sepsis) where surgical consultation and inpatient ICU-level management dominate the case, with asymptomatic *C. difficile* carriage (positive PCR but no clinical CDI), with documented severe hypersensitivity to fidaxomicin, with a non-CDI cause of diarrhea, or where antibiotic stewardship has not approved fidaxomicin, the operational pathway shifts:

- Oral vancomycin 125 mg PO QID for 10 days for non-severe CDI as the cost-effective alternative.
- IV metronidazole plus oral vancomycin for severe or fulminant CDI alongside surgical consultation.
- Faecal microbiota transplant (FMT) for multi-recurrent CDI at KFSHRC Riyadh.
- Bezlotoxumab (Zinplava) IV single infusion as adjunctive recurrence prevention in selected high-risk adults where available.
- Discontinuation or de-escalation of the precipitating antibiotic.
- Hospital admission for source control where the case profile requires it.

Reserve Meds does not promote one antibiotic over another.

## What Reserve Meds does on this case

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We are a US-based concierge coordinator. On a KSA Dificid case we build the documentation pack with the treating infectious diseases or gastroenterology office, confirm Saudi SFDA registration status and the appropriate supply pathway (formulary stock at the prescribing tertiary centre where available, named-patient European import via Dificlir ex-EU where not), coordinate the named-patient supply order through licensed regional specialty distributors where required, support the antibiotic stewardship sign-off conversation by helping assemble the documentation pack the committee needs, run the insurance or state-funded pre-authorisation conversation with the total-cost-of-care framing, organise the baseline severity assessment, coordinate inpatient-to-outpatient handoff as the patient transitions to home completion of the course, and stay with the case through the day 10 cure assessment and day 28 recurrence assessment with handoff to the local prescriber for ongoing surveillance. Clinical decisions remain with your treating infectious diseases or gastroenterology specialist.

### *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.

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### **Reserve Meds**

*reserved for you.*

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.

Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.

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