

Hikma launches Fidaxomicin Tablets in the US

London, UK, 15 October 2026 – Hikma Pharmaceuticals PLC (Hikma, Group), a multinational pharmaceutical company, today announced the US launch of Fidaxomicin Tablets in 200mg, expanding its US portfolio.

The product is indicated in adults for the treatment of *Clostridioides difficile*-associated diarrhea (CDAD). Please see below for Important Safety Information and refer to the full Prescribing Information at <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d773c5ee-9361-49b0-871b-af34f3f936be>.

"*C. difficile* infection is a serious and often recurring condition, and hospitals, clinicians and patients need dependable access to effective treatment options," said Hafrun Fridriksdottir, US President and Chief R&D Officer at Hikma. "Fidaxomicin is an important addition to our portfolio, and it helps broaden access to this medicine for patients across the US. We are manufacturing Fidaxomicin Tablets in the US, at our state-of-the-art facility in Columbus, Ohio, furthering Hikma's position as one of the nation's largest domestic producers of high-quality essential generic medicines."

According to IQVIA, US sales of Fidaxomicin Tablets were approximately \$360 million in the 12 months ending June 2026.

Hikma supplies a broad range of increasingly complex non-injectable products to the US market. Our Columbus, Ohio facility supports this portfolio, and we are committed to continued investment in US manufacturing.

– ENDS –

This product has been approved for marketing in the United States by the US FDA. This product approval does not confer the right on Hikma, or any other party, to market this product outside the United States.

About Hikma

Hikma helps put better health within reach every day for millions of people around the world. For more than 45 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are a global company with a local presence across North America, the Middle East and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non-branded generic medicines. Together, our 9,400 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit: www.hikma.com

Hikma Pharmaceuticals PLC (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (LEI:549300BNS685UXH4JI75) (rated BBB/stable S&P and BBB/stable Fitch)

HK-3671

Enquiries

Hikma Pharmaceuticals PLC

Susan Ringdal
EVP, Strategic Planning and Global Affairs

+44 (0)20 7399 2760/ +44 7776 477050

Steven Weiss
US Communications

+1 732 788 8279

IMPORTANT SAFETY INFORMATION FOR FIDAXOMICIN TABLETS

CONTRAINDICATIONS

Fidaxomicin is contraindicated in patients who have known hypersensitivity to fidaxomicin or any other ingredient in fidaxomicin tablets.

WARNINGS AND PRECAUTIONS

- **Hypersensitivity Reactions**

Acute hypersensitivity reactions, including dyspnea, rash, pruritus, and angioedema of the mouth, throat, and face have been reported with fidaxomicin. If a severe hypersensitivity reaction occurs, fidaxomicin should be discontinued and appropriate therapy instituted.

Some patients with hypersensitivity reactions to fidaxomicin also reported a history of allergy to other macrolides. Physicians prescribing fidaxomicin to patients with a known macrolide allergy should be aware of the possibility of hypersensitivity reactions.

- **Not for Use in Infections Other than *Clostridioides difficile*-Associated Diarrhea (CDAD)**

Fidaxomicin is not expected to be effective for the treatment of other types of infections. Fidaxomicin should only be used for the treatment of CDAD.

- **Development of Drug-Resistant Bacteria**

Prescribing fidaxomicin in the absence of proven or strongly suspected *C. difficile* infection is unlikely to benefit the patient and increases the risk of the development of drug-resistant bacteria.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Adults

The safety of fidaxomicin 200 mg tablets taken twice daily for 10 days was evaluated in 564 adult patients with CDAD in two active-controlled trials with 86.7% of patients receiving a full course of treatment.

Thirty-three (33) adult patients receiving fidaxomicin (5.9%) withdrew from trials as a result of adverse reactions. The following adverse reactions were reported in $\geq 2\%$ of adult patients taking fidaxomicin tablets in controlled trials:

Gastrointestinal Disorders: nausea, vomiting, abdominal pain, gastrointestinal hemorrhage

Blood and Lymphatic System Disorders: anemia, neutropenia

The following adverse reactions were reported in $<2\%$ of adult patients taking fidaxomicin tablets in controlled trials:

Gastrointestinal Disorders: abdominal distension, abdominal tenderness, dyspepsia, dysphagia, flatulence, intestinal obstruction, megacolon

Investigations: increased blood alkaline phosphatase, decreased blood bicarbonate, increased hepatic enzymes, decreased platelet count

Metabolism and Nutrition Disorders: hyperglycemia, metabolic acidosis

Skin and Subcutaneous Tissue Disorders: drug eruption, pruritus, rash

See the [Full Prescribing Information](#) for fidaxomicin tablets for more information about these trials.

Post Marketing Experience

The following adverse reactions have been identified during post-approval use of fidaxomicin. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Hypersensitivity reactions (dyspnea, angioedema, rash, pruritus)

Pediatric use information is approved for Cubist Pharmaceuticals LLC's DIFICID® (fidaxomicin) tablets. However, due to Cubist Pharmaceuticals LLC's marketing exclusivity rights, this drug product is not labeled with that information.

DRUG INTERACTIONS

Fidaxomicin and its main metabolite, OP-1118, are substrates of P-glycoprotein (P-gp), which is expressed in the gastrointestinal tract.

- **Cyclosporine**

Cyclosporine is an inhibitor of multiple transporters, including P-gp. When cyclosporine was co-administered with fidaxomicin, plasma concentrations of fidaxomicin and OP-1118 were significantly increased but remained in the ng/mL range. Concentrations of fidaxomicin and OP-1118 may also be decreased at the site of action (i.e., gastrointestinal tract) via P-gp inhibition; however, concomitant P-gp inhibitor use had no attributable effect on safety or treatment outcome of fidaxomicin-treated adult patients in controlled clinical trials. Based on these results, fidaxomicin may be co-administered with P-gp inhibitors and no dose adjustment is recommended.

USE IN SPECIFIC POPULATIONS

- **Pregnancy**

The limited available data on use of fidaxomicin in pregnant women are insufficient to inform any drug-associated risk for major birth defects, miscarriage, or adverse maternal or fetal outcomes.

- **Lactation**

There is no information on the presence of fidaxomicin or its main metabolite, OP-1118, in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for fidaxomicin and any potential adverse effects on the breastfed infant from fidaxomicin or from the underlying maternal condition.

- **Pediatric Use**

The safety and effectiveness of fidaxomicin in pediatric patients have not been established in patients younger than 6 months of age.

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- **Geriatric Use**

No overall differences in safety or effectiveness of fidaxomicin compared to vancomycin were observed between younger patients and those 65 years of age and older.

PATIENT COUNSELING INFORMATION

When fidaxomicin tablets are prescribed to treat a *C. difficile* infection, patients should be told that, although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by fidaxomicin tablets or other antibacterial drugs in the future.

For more information, please see the [Full Prescribing Information](#) for fidaxomicin tablets.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <https://www.fda.gov/medwatch> or call 1-800-FDA-1088.

For more information about fidaxomicin tablets, please contact Hikma Pharmaceuticals USA Inc. at 1-800-962-8364.

Distributed by: Hikma Pharmaceuticals USA Inc.; Berkeley Heights, NJ 07922

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