



PRODUCT NAME :	FIDAXOMICIN TABLETS	COUNTRY : US	LOCATION : Dahej	Supersedes AW No.:			
ITEM / PACK :	Outsert	NO. OF COLORS: 1	REMARK : V. No. : 01				
DESIGN STYLE :	Back Side	PANTONE SHADE NOS.:	SUBSTRATE : 40 g/m2 Bible Paper				
CODE :	8106978	■ Black	Activities	Department	Name	Signature	Date
DIMENSIONS (MM) :	525 x 340		Prepared By	Pkg. Dev.			
ART WORK SIZE :	S/S		Reviewed By	Pkg. Dev.			
DATE :	13-01-2026	Font Size 6 pt_Med. 10 pt	Approved By	Quality			

Note: Pharma code/ Bar code and adjacent text must be visible on folded leaflet.
These details can be moved by printed to arrange pharma code/ Bar code and adjacent text visible on folded leaflet.

- If you are pregnant, you and your doctor should decide together if you will take fidaxomicin tablets.

Breastfeeding

- If you are breastfeeding or plan to breastfeed, tell your doctor before you take fidaxomicin tablets.
- It is not known if fidaxomicin passes into breast milk.
- If you are breastfeeding, you and your doctor should decide together if you will take fidaxomicin tablets.

Other Medicines

- **Tell your doctor about all of the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal and dietary supplements.
- Know the medicines you take. Keep a list of your medicines to show your doctor and pharmacist when you get a new medicine.

Allergic Reactions

- See **"Who should not take fidaxomicin tablets?"**
- If you are allergic to other kinds of antibiotics called macrolides (for example: azithromycin (Zithromax) or clarithromycin (Biaxin)) or any other ingredient in fidaxomicin tablets, tell your doctor. See the end of this Patient Information for a complete list of ingredients in fidaxomicin tablets.

How do I take fidaxomicin tablets?

- Take fidaxomicin tablets exactly as prescribed by your doctor.
- Take fidaxomicin tablets twice a day (approximately every 12 hours). For example, if you take your first dose at 8:00 a.m. you should take your second dose at 8:00 p.m.
- You can take fidaxomicin tablets with or without food.
- **Do not** skip any doses or stop taking fidaxomicin tablets until you finish your prescribed treatment, even if you begin to feel better, unless you have a serious allergic reaction (see **"What are the possible side effects of fidaxomicin tablets?"**).

This will lower the chance that the bacteria will become resistant to fidaxomicin tablets. If this happens, fidaxomicin tablets and other antibiotic medicines may not work in the future.

What are the possible side effects of fidaxomicin tablets?

Fidaxomicin tablets can cause serious side effects, including:

- **Allergic reaction.** If you get a severe allergic reaction while taking fidaxomicin tablets, including problems breathing or shortness of breath, rash, itching or hives, or swelling of the mouth, throat, or face, stop taking fidaxomicin tablets and get emergency medical help right away.

Common side effects of fidaxomicin tablets include:

The most common side effects of fidaxomicin tablets in **adults** include:

- nausea
- vomiting
- stomach pain
- bleeding in the stomach or intestines
- low red blood cell count (anemia)
- low white blood cell count (neutropenia)

Other less common side effects of fidaxomicin tablets may include:

- swelling of any body part (such as your face, lips, tongue or around your eyes)
- itching
- hives
- bloating
- stomach tenderness
- heartburn
- problems swallowing
- passing gas
- intestinal blockage
- serious bowel inflammation (toxic megacolon)
- low platelet count (important for clotting and to control bleeding)
- high levels of acid in your blood (metabolic acidosis)
- high blood sugar (hyperglycemia)
- abnormal liver tests
- low levels of blood bicarbonate

If you have any side effect that bothers you or does not go away, tell your doctor.

There may be other side effects to fidaxomicin tablets that are not listed. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store fidaxomicin tablets?

- Store fidaxomicin tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep fidaxomicin tablets in its original bottle until you are ready to take it.

Keep fidaxomicin tablets and all medicines out of the reach of children.

General information about the safe and effective use of fidaxomicin tablets.

Medicines are sometimes prescribed for purposes other than those listed in the Patient Information. Do not take fidaxomicin tablets for a condition for which it was not prescribed. Do not give fidaxomicin tablets to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or doctor for information about fidaxomicin tablets that is written for health professionals.

What if I have questions?

- Call your doctor.
- Call Torrent, the company that makes fidaxomicin tablets, at 1-800-912-9561.
- Go to the website – www.torrentpharma.com.
- You can also find the full prescribing information written for doctors at www.torrentpharma.com

What are the ingredients in fidaxomicin tablets?

- **Active ingredient:** fidaxomicin.
- **Inactive ingredients:** butylated hydroxyl toluene, hydroxypropyl cellulose, lecithin (soya), magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, sodium starch glycolate, talc and titanium dioxide.

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Manufactured by:

Torrent Pharmaceuticals LTD., Bharuch-392130, India.

Manufactured for:

Torrent Pharma INC., Basking Ridge, NJ 07920.

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Revised: January 2026

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.

This Patient Information has been approved by the U.S. Food and Drug Administration