

Patient Information
DIFICID[®] (dih-fih-sid)
(fidaxomicin)
tablets, for oral use

What You Need to Know About Your Medicine

- Before you take DIFICID, be sure you understand what it is for and how to take it.
- If you have questions about DIFICID, ask your doctor or pharmacist.
- Remember that your doctor has prescribed DIFICID only for you. Never give this medicine to anyone else.
- Keep this Patient Information for DIFICID so you can read it again.

What is DIFICID?

DIFICID is an antibiotic medicine used to treat an infection called *Clostridium difficile*-associated diarrhea (CDAD) in adults 18 years of age and older. *Clostridium difficile* (C-diff) is a bacterium that can cause an infection that can damage your colon and cause stomach pain and severe diarrhea.

- DIFICID is not to be used to treat other types of infections in the body.
- Sometimes infections are caused by viruses rather than bacteria. Antibiotic medicines including DIFICID do not kill viruses.

It is not known if DIFICID is safe and effective in children under 18 years old.

Who should not take DIFICID?

Do not take DIFICID if you are allergic to fidaxomicin, or any other ingredient in DIFICID. See the end of this Patient Information for a complete list of ingredients in DIFICID.

What should I tell my doctor before taking DIFICID?

Pregnancy

- If you are pregnant or plan to become pregnant, tell your doctor before you take DIFICID.
- It is not known if DIFICID will harm your baby while you are pregnant.
- If you are pregnant, you and your doctor should decide together if you will take DIFICID.

Breastfeeding

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

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 DIFICID?**”
- If you are allergic to other kinds of antibiotics called macrolides (for example: azithromycin (Zithromax) or clarithromycin (Biaxin)) or any other ingredient in DIFICID, tell your doctor. See the end of this Patient Information for a complete list of ingredients in DIFICID.

How do I take DIFICID?

- Take DIFICID exactly as prescribed by your doctor.
- Take 1 tablet twice a day (approximately every 12 hours). For example, if you take your first tablet at 8:00 a.m. you should take your second tablet at 8:00 p.m.
- You can take DIFICID with or without food.
- **Do not** skip any doses or stop taking DIFICID 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 DIFICID?**”).
This will lower the chance that the bacteria will become resistant to DIFICID. If this happens, DIFICID and other antibiotic medicines may not work in the future.

What are the possible side effects of DIFICID?

DIFICID can cause serious side effects, including:

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

Common side effects of DIFICID include:

The most common side effects of DIFICID include:

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

Other less common side effects of DIFICID may include:

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

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| <p>If you have any side effect that bothers you or does not go away, tell your doctor.</p> |
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There may be other side effects to DIFICID 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 DIFICID?

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

Keep DIFICID and all medicines out of the reach of children.

General information about the safe and effective use of DIFICID.

Medicines are sometimes prescribed for purposes other than those listed in the Patient Information. Do not take DIFICID for a condition for which it was not prescribed. Do not give DIFICID 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 DIFICID that is written for health professionals.

What if I have questions?

- Call your doctor.
- Call Merck, the company that makes DIFICID, at 1-800-444-2080.
- Go to the website – www.DIFICID.com.
- You can also find the full prescribing information written for doctors at www.DIFICID.com

What are the ingredients in DIFICID?

- **Active ingredient:** fidaxomicin.
 - **Inactive ingredients:** butylated hydroxytoluene, hydroxypropyl cellulose, lecithin (soy), magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, sodium starch glycolate, talc, and titanium dioxide.
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Manuf. for: Merck Sharp & Dohme Corp., a subsidiary of
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Manufactured by: Patheon Inc., Mississauga, Ontario, L5N 7K9 Canada

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usppi-mk5119-t-1904r000

This Patient Information has been approved by the U.S. Food and Drug Administration
Issued: 04/2019