

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

PrDIFICID®
(fidaxomicin)

Read this carefully before you start taking **DIFICID®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **DIFICID®**.

What is DIFICID® used for?

DIFICID® is used in adults to treat colon (large intestine) infections that are caused by certain bacteria called *Clostridium difficile*. This serious illness can result in painful, severe diarrhea.

Antibacterial drugs like DIFICID® treat only bacterial infections. They do not treat viral infections such as the common cold.

How does DIFICID® work?

DIFICID® contains an antibiotic that reduces infections by:

- Stopping the growth of bacteria.
- Killing bacteria.

What are the ingredients in DIFICID®?

Medicinal ingredients: fidaxomicin

Non-medicinal ingredients: butylated hydroxytoluene, hydroxypropyl cellulose, lecithin (soy), magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinised starch, sodium starch glycolate, talc and titanium dioxide.

DIFICID® comes in the following dosage forms:

Tablets: 200 mg

Do not use DIFICID® if:

If you are allergic (hypersensitive) to fidaxomicin, or any of the other ingredients of DIFICID®.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take DIFICID®. Talk about any health conditions or problems you may have, including if you:

- Have a known allergy to other antibiotics.
- Have had a previous gut infection (such as *Clostridium difficile*).
- Are pregnant or think you may be pregnant, ask your doctor or pharmacist for advice before taking this medicine. You should not take DIFICID® if you are pregnant, unless your doctor tells you otherwise.
- Are breastfeeding ask your doctor or pharmacist for advice before taking this medicine. It is not known whether fidaxomicin passes into breast milk.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take DIFICID®:

- Although you may feel better early in treatment, DIFICID® should be used exactly as directed.
- Misuse or overuse of DIFICID® could lead to the growth of bacteria that will not be killed by DIFICID® (resistance). This means that DIFICID® may not work for you in the future.
- Do not share your medicine.
- Swallow the tablets whole with a glass of water. You can take DIFICID® with or without food.

Usual dose:

One tablet (200 mg) every 12 hours for 10 days.

Overdose:

If you think you have taken too much DIFICID®, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

Take the tablet as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

What are possible side effects from using DIFICID®?

These are not all the possible side effects you may feel when taking DIFICID®. If you experience any side effects not listed here, contact your healthcare professional.

DIFICID® may cause the following side effects:

- nausea, constipation, vomiting
- decreased appetite
- dizziness, headache
- dry mouth, altered taste (dysgeusia)
- bloated feeling, wind (flatulence)

DIFICID® can cause abnormal blood test results (i.e., increased or abnormal liver enzymes). Your doctor will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE Severe Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after “EXP”.

DIFICID[®] should be stored at room temperature (15° to 30°C) in a tightly closed container away from heat and direct light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

If you want more information about DIFICID[®]:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer’s website www.merck.ca or by calling 1-800-567-2594.

To report an adverse event related to DIFICID[®], please contact 1-800-567-2594.

This leaflet was prepared by Merck Canada Inc.

Last Revised March 29, 2019

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