

PART III: CONSUMER INFORMATION**Pr DIFICID[®]
(fidaxomicin)**

This leaflet is part III of a three-part "Product Monograph" published when DIFICID[®] was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about DIFICID[®]. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

DIFICID[®] is used in adults to treat infections of the lining of the colon (large intestine) with 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. 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.

What it does:

DIFICID[®] is used to kill the bacteria which cause *Clostridium difficile* infections.

When it should not be used:

If you are allergic (hypersensitive) to the active substance fidaxomicin, or any of the other ingredients of DIFICID[®] (see **What the nonmedicinal ingredients are**).

What the medicinal ingredient is:

fidaxomicin

What the nonmedicinal ingredients are:

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

What dosage forms it comes in:

Tablets: 200 mg

WARNINGS AND PRECAUTIONS

BEFORE you use DIFICID[®] talk to your doctor or pharmacist:

- If you have severe kidney problems or severe liver problems
- If you have inflammatory bowel disease
- If you have any allergies to this drug or its ingredients or components of the container

- If you have a known allergy to other antibiotics
- If you 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.
- If you are breastfeeding ask your doctor or pharmacist for advice before taking this medicine. It is not known whether fidaxomicin passes into breast milk.
- DIFICID[®] should not be used in children or adolescents less than 18 years of age, as there is no information on the use in that population.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

PROPER USE OF THIS MEDICATION**Usual adult dose:**

The recommended dose is one tablet (200 mg) twice daily (one tablet every 12 hours) for 10 days.

Swallow the tablets whole with a glass of water. You can take DIFICID[®] before, during or after meals.

Full course of medication should be completed as prescribed.

Overdose:

In case of drug overdose, contact a health care practitioner, 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor, nurse, or pharmacist		Stop taking drug and seek 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			√

This is not a complete list of side effects. For any unexpected effects while taking DIFICID[®], contact your doctor or pharmacist.

HOW TO STORE IT

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”. The expiry date refers to the last day of that month.

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.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](#);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

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.

MORE INFORMATION

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 Consumer Information by visiting the [Health Canada website](#) or 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.

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