

DIFICID®

fidaxomicin tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about fidaxomicin tablets.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking DIFICID against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What DIFICID is used for

This medicine is used 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 diarrhoea.

DIFICID contains the active ingredient fidaxomicin.

Fidaxomicin is an antibiotic that belongs to a new group of medicines called macrocyclic antibiotics.

It works by killing the bacteria which cause *Clostridium difficile* infections. DIFICID will not work against viral infections such as colds or flu or against infections with other types of bacteria.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is only available with a doctor's prescription.

There is no evidence that this medicine is addictive.

Before you take DIFICID

When you must not take it

Do not take this medicine if you have an allergy to:

- Fidaxomicin
- Any of the other ingredients of DIFICID listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- any liver problems
- any kidney problems
- inflammatory bowel disease.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breastfeeding or are planning to breastfeed.

It is not known whether fidaxomicin passes into breast milk. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking DIFICID.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

How to take DIFICID

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

Follow the instructions they give you.

If you take the wrong dose, DIFICID may not work as well and your problem may not improve.

How much to take

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

How to take it

Swallow the tablets whole with a glass of water.

When to take it

This medicine may be taken with or without food.

How long to take it

Continue taking your medicine until you finish the pack or for as long as your doctor tells you.

If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

Do not stop taking it because you are feeling better.

If you forget to take it

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 the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre in Australia (telephone 13 11 26), or the New Zealand National Poisons Centre (telephone 0800 764 766 or go to www.poisons.co.nz) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much DIFICID. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking DIFICID

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking DIFICID.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

Things you must not do

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you do not complete the full course prescribed by your doctor, all the organisms causing your infection may not be killed. These organisms may continue to grow and multiply so that your infection may not clear completely or may return.

Do not take DIFICID to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking DIFICID.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea
- vomiting
- constipation
- headache
- dizziness

These are mild side effects of the medicine, and are short-lived.

Tell your doctor immediately or go to Accident & Emergency at your nearest hospital if you notice any of the following:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

The above list are signs of a serious allergic reaction, which may require medical attention. Serious side effects are rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking DIFICID

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store DIFICID or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres (about 5 feet) above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

- Magnesium Stearate
- Polyvinyl Alcohol
- Titanium Dioxide
- Talc
- Macrogol 3350
- Lecithin (Soy)

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

In Australia:

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Australian Register Number

200 mg film-coated tablet (bottle):

AUST R 195623

200 mg film-coated tablet (blister pack): AUST R 195622

Product description

What it looks like

DIFICID 200 mg are white, oblong tablets; each tablet is marked with "FDX" on one side and "200" on the other side. They are available in bottles of 20 or 60 tablets and blister packs of 20 or 100 tablets. Not all packs may be marketed.

Ingredients

Active ingredient:

- Fidaxomicin 200 mg

Inactive ingredients:

- Microcrystalline Cellulose
- Pregelatinised maize starch
- Hydroxypropylcellulose
- Butylated Hydroxytoluene
- Sodium Starch Glycollate