

DIFICID®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking DIFICID?

DIFICID contains the active ingredient fidaxomicin. DIFICID is used to treat infections of the lining of the colon (large intestine) with certain bacteria called *Clostridium difficile*.

For more information, see Section [1. Why am I taking DIFICID?](#) in the full CMI.

2. What should I know before I take DIFICID?

Do not use if you have ever had an allergic reaction to DIFICID or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take DIFICID?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DIFICID and affect how it works.

Tell your doctor or pharmacist if you are taking any other medicines. For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take DIFICID?

- Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.
- The usual dose is one tablet (200 mg) twice daily (one tablet every 12 hours) for 10 days.

More instructions can be found in Section [4. How do I take DIFICID?](#) in the full CMI.

5. What should I know while taking DIFICID?

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|-----------------------------|--|
| Things you should do | <ul style="list-style-type: none">• If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking DIFICID. |
|-----------------------------|--|

| | |
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| <p>Things you should not do</p> | <ul style="list-style-type: none"> • Do not stop taking your medicine or lower the dosage without checking with your doctor. • Do not take DIFICID to treat any other complaints unless your doctor tells you to. |
| <p>Driving or using machines</p> | <ul style="list-style-type: none"> • Be careful driving or operating machinery until you know how DIFICID affects you. • DIFICID is not expected to affect your ability to drive, use tools or machines. |
| <p>Looking after your medicine</p> | <ul style="list-style-type: none"> • Keep your medicine in the original container. • If you take it out of its original container it may not keep well. |

For more information, see Section [5. What should I know while taking DIFICID?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist if you notice any of the following and they worry you: nausea, vomiting, constipation, headache, dizziness.

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.

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

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

DIFICID®

Active ingredient: *fidaxomicin*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking DIFICID. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking DIFICID.**

Where to find information in this leaflet:

- [1. Why am I taking DIFICID?](#)
- [2. What should I know before I take DIFICID?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take DIFICID?](#)
- [5. What should I know while taking DIFICID?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking DIFICID?

DIFICID contains the active ingredient fidaxomicin. DIFICID 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.

DIFICID 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.

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.

2. What should I know before I take DIFICID?

Warnings

Do not take DIFICID if:

- **you are allergic to Fidaxomicin, or any of the ingredients listed at the end of this leaflet.**
- Always check the ingredients to make sure you can use this medicine.

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

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

Check with your doctor if you:

- **have allergies to any other medicines, foods, preservatives or dyes.**

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

Addiction

There is no evidence that this medicine is addictive.

3. What if I am taking other medicines?

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DIFICID.

4. How do I take DIFICID?

How much to take

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.

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

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

When to take DIFICID

This medicine may be taken with or without food.

How to take DIFICID

Swallow the tablets whole with a glass of water.

How long to take DIFICID

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 DIFICID

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 DIFICID

If you think that you have taken too much DIFICID, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking DIFICID?

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

Call your doctor straight away if you:

- become pregnant while taking this medicine

Remind any doctor, dentist or pharmacist you visit that you are taking DIFICID.

Things you should 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.**

Driving or using machines

Be careful driving or operating machinery until you know how DIFICID affects you.

DIFICID is not expected to affect your ability to drive, use tools or machines.

Looking after your medicine

- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Mild side effects

| Mild side effects | What to do |
|---|---|
| <ul style="list-style-type: none">● nausea● vomiting● constipation● headache● dizziness <p>These are mild side effects of the medicine and are short-lived.</p> | <p>Speak to your doctor if you have any of these mild side effects and they worry you.</p> |

Serious side effects

| Serious side effects | What to do |
|--|--|
| <ul style="list-style-type: none">● 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 <p>These are signs of a serious allergic reaction, which may require medical</p> | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

| Serious side effects | What to do |
|---|-------------------|
| attention. Serious side effects are rare. | |

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What DIFICID contains

| | |
|--|--------------------|
| Active ingredient (main ingredient) | Fidaxomicin 200 mg |
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| | |
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| <p>Other ingredients (inactive ingredients)</p> | <p>Microcrystalline Cellulose</p> <p>Pregelatinised maize starch</p> <p>Hyprolose</p> <p>Butylated Hydroxytoluene</p> <p>Sodium Starch Glycollate</p> <p>Magnesium Stearate</p> <p>Tablet Coating:</p> <p>Polyvinyl Alcohol</p> <p>Titanium Dioxide</p> <p>Purified Talc</p> <p>Macrogol 3350</p> <p>Lecithin (Soy)</p> |
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This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What DIFICID looks like

DIFICID 200 mg are white to off-white film-coated, 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. Not all pack sizes may be marketed.

DIFICID 200 mg film-coated tablet (bottle): AUST R
195623

Who distributes DIFICID

Merck Sharp & Dohme (Australia) Pty Limited
Level 1, Building A, 26 Talavera Road
Macquarie Park NSW, 2113, Australia

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