
PROPOSED ANNOTATED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

FIDICID 200 mg, film-coated tablets

Fidaxomicin

Sugar free

Read all of this leaflet carefully before you start taking FIDICID 200 mg

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- FIDICID 200 mg has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What FIDICID 200 mg is and what it is used for
2. What you need to know before you take FIDICID 200 mg
3. How to take FIDICID 200 mg
4. Possible side effects
5. How to store FIDICID 200 mg
6. Contents of the pack and other information

1. What FIDICID 200 mg is and what it is used for

FIDICID 200 mg 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 diarrhoea. FIDICID 200 mg works by killing the bacteria that cause the infection and helps to reduce the associated diarrhoea.

2. What you need to know before you take FIDICID 200mg

Do not take FIDICID 200 mg:

- if you are hypersensitive (allergic) to the active ingredient, fidaxomicin or to any of the other ingredients of FIDICID 200 mg (see section 6).

Warnings and precautions

Take special care with FIDICID 200 mg.

If you feel that you might have a severe allergic reaction such as trouble breathing (dyspnoea), swelling of the face or throat (angioedema), severe rash or severe itching (pruritus), stop taking FIDICID 200 mg and seek medical advice urgently from your doctor, pharmacist or at your local hospital emergency department (see section 4).

Talk to your doctor or pharmacist before taking FIDICID 200 mg:

- if you are allergic to macrolides (a class of antibiotics e.g. erythromycin), ask your doctor for advice before using this medicine. Your doctor will tell you whether this medicine is suitable for you;
- if you have kidney or liver problems, ask your doctor for advice before taking FIDICID 200 mg. Your doctor will tell you whether FIDICID 200 mg is suitable for you.

There are limited data available on the use of FIDICID 200 mg in severe cases of the disease (e.g., pseudomembranous colitis). Your doctor will know whether your disease falls in the severe categories and will tell you whether FIDICID 200 mg is suitable for you.

Children and adolescents

Do not give FIDICID 200 mg to children below the age of 18 years because the safety and efficacy has not yet been established.

Other medicines and FIDICID 200 mg

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

FIDICID 200 mg blood levels can be affected by other medicines you take, and blood levels of other medicines can be affected by taking FIDICID 200 mg. Examples of such medicines are:

- ciclosporin (a medicine used to dampen down the body's immune reactions, used e.g. after an organ or bone marrow transplant, for psoriasis or eczema, or for rheumatoid arthritis or nephrotic syndrome)
- ketoconazole (a medicine used to treat fungal infections)
- erythromycin (a medicine used to treat ear, nose, throat, chest and skin infections)
- clarithromycin (a medicine used to treat chest infections, throat and sinus infections, skin and tissue infections and *Helicobacter pylori* infections associated with duodenal or stomach ulcer)
- verapamil (a medicine used to treat high blood pressure or to prevent chest pain attacks, or used following a heart attack to prevent another one)
- dronedarone and amiodarone (medicines used to control the heartbeat)
- dabigatran etexilat (a medicine used to prevent the formation of blood clots after hip or knee replacement surgery)
- digoxin (a medicine used to treat heart failure and an irregular heartbeat) may slightly increase digoxin levels in the blood, but it's unlikely to have a noticeable impact on digoxin's effectiveness.

You should not use FIDICID 200 mg in combination with one of these medicines, unless your doctor tells you otherwise. If you use one of these medicines, please ask your doctor for advice before taking FIDICID 200 mg.

FIDICID 200 mg with food and drink

FIDICID 200 mg can be taken with or without food.

Pregnancy, breastfeeding and fertility

Safety and efficacy in pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking FIDICID 200 mg.

No special hazard to fertility is known.

Driving and using machines

FIDICID 200 mg causes dizziness. This may affect your ability to drive, use tools or machinery.

It is not always possible to predict to what extent FIDICID 200 mg may interfere with your daily activities.

You should ensure that you do not engage in the above activities until they are aware of the measure to which FIDICID 200 mg affects them.

3. How to take FIDICID 200 mg

Do not share medicines prescribed for you with any other person.

Instructions for proper use

Always take FIDICID 200 mg exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual 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 FIDICID 200 mg before, during or after meals.

Your doctor will tell you how long your treatment with FIDICID 200 mg will last. If you have the impression that the effect of FIDICID 200 mg is too strong or too weak, talk to your doctor or pharmacist.

If you take more FIDICID 200 mg than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take the medicine pack with you so the healthcare professional knows what you have taken.

If you forget to take FIDICID 200 mg

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.

If you stop taking FIDICID 200 mg

Do not stop taking FIDICID 200 mg, unless your doctor has advised you to do so.

Keep taking FIDICID 200 mg until the course is finished, even if you feel better.

If you stop taking FIDICID 200 mg too soon, the infection may come back.

4. Possible side effects

FIDICID 200 mg can have side effects.

Not all side effects reported for FIDICID 200 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FIDICID 200 mg, please consult your healthcare provider for advice.

If any of the following happens, stop taking FIDICID 200 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- trouble breathing (dyspnoea);
- swelling of the face or throat (angioedema);
- severe rash or severe itching (pruritus).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to FIDICID 200 mg. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- vomiting, nausea and constipation;
- certain blood tests might show changed levels, e.g., increased or abnormal liver enzymes (alanine aminotransferase).

Less frequent side effects:

- decreased appetite;
- dizziness, headache;
- dry mouth, altered taste (dysgeusia);
- bloated feeling, wind (flatulence);
- rash, itching (pruritus).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to you doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of FIDICID 200 mg.

5. How to store FIDICID 200 mg

- Store all medicines out of reach of children.
- Do not use FIDICID 200 mg after the expiry date which is stated on the carton, blister or bottle after EXP.

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

- Store at or below 25 °C.

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- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Content of the pack and other information

What FIDICID 200 mg contains

- The active substance is fidaxomicin.

Each film-coated tablet contains 200 mg fidaxomicin.

- The other ingredients are:

- *Core tablets:* butylated hydroxytoluene, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, pregelatinised starch, sodium starch glycolate.
- *Coating:* lecithin (soy), polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide.

What FIDICID 200 mg looks like and contents of the pack

White to off-white film-coated modified capsule shaped tablet debossed with “FDX” on one side and “200” on the other side.

FIDICID 200 mg is presented as 20 x 1 film-coated tablet in alu/alu perforated unit dose blisters (10 film-coated tablets per blister card; 2 blister cards per carton).

Holder of Certificate of Registration

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FIDICID 200 mg, film-coated tablets (47/20.3/1137)
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