

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

FIDICID 200 mg film- coated tablet

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 or your pharmacist.
- 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.

1. WHAT FIDICID 200 mg CONTAINS:

The active substance is: 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.

2. WHAT FIDICID 200 mg 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.

3. BEFORE YOU TAKE FIDICID 200 mg

Do not take FIDICID 200 mg:

- if you are hypersensitive (allergic) to the active ingredient, fidaxomicin or to any of the other ingredients.

Take special care with FIDICID 200 mg:

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.

If, next to your infection of the large intestine, you also have an inflammation of the intestines (inflammatory bowel disease), 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.

Taking FIDICID 200 mg with food and drink:

FIDICID 200 mg can be taken with or without food.

Pregnancy and Breastfeeding

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

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking FIDICID 200 mg.

Driving and using machinery:

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

Using other medicines with FIDICID 200 mg:

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

FIDICID 200 mg may interfere with medicines that interact with a particular protein in your body, the so called P-glycoprotein. Examples of such medicines are:

- dabigatran etexilat (a medicine used to prevent the formation of blood clots after hip or knee replacement surgery)

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.

4. 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 has told you. You should check with your doctor or pharmacist if you are not sure.

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 FIDICID 200 mg before, during or after meals.

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

No cases of acute overdose have been reported.

As a precaution, talk to a doctor. Take the medicine pack with you so the doctor knows what you have taken.

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

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.

5. 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 while taking FIDICID 200 mg, please consult your doctor, pharmacist or other healthcare professional for advice.

The most **frequent side effects** reported during clinical trials were:

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

Other possible side effects are the following:

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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

6. STORING AND DISPOSING OF FIDICID 200 mg

Keep 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
- 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.

7. PRESENTATION OF FIDICID 200 mg

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).

8. IDENTIFICATION OF FIDICID 200 mg

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

9. REGISTRATION NUMBER

47/20.3/1137

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Equity Pharmaceuticals (Pty) Ltd.

100 Sovereign Drive

Route 21, Corporate Park

Nellmapius Drive, Irene

Pretoria

0157

11. DATE OF PUBLICATION

23 Nov 2017