

Package leaflet: Information for the user

DIFICLIR 200 mg film-coated tablets

Fidaxomicin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What DIFICLIR is and what it is used for
2. What you need to know before you take DIFICLIR
3. How to take DIFICLIR
4. Possible side effects
5. How to store DIFICLIR
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1. What DIFICLIR is and what it is used for

DIFICLIR is an antibiotic which contains the active substance fidaxomicin.

DIFICLIR 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. DIFICLIR 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 DIFICLIR

Do not take DIFICLIR

- If you are allergic to fidaxomicin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking DIFICLIR.

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

If you are allergic to macrolides (a class of antibiotics), 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 using this medicine. Your doctor will tell you whether this medicine is suitable for you.

There are limited data available on the use of fidaxomicin 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 this medicine is suitable for you.

Children and adolescents

DIFICLIR should not be used in children or adolescents aged below 18 years as there is no information on this use in this population.

Other medicines and DIFICLIR

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

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

- cyclosporin (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)

You should not use DIFICLIR 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 this medicine.

Pregnancy and breast-feeding

You should not take DIFICLIR if you are pregnant, unless your doctor tells you otherwise.

This is because it is not known whether fidaxomicin can harm your baby.

If you are pregnant or think you may be pregnant, ask your doctor or pharmacist for advice before taking this medicine.

It is not known whether fidaxomicin passes into breast milk, but it is not expected to do so.

If you are breastfeeding ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

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

3. How to take DIFICLIR

Always take this medicine 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 DIFICLIR before, during or after meals.

If you take more DIFICLIR than you should

If you have taken more tablets than you should have, talk to a doctor. Take the medicine pack with you so the doctor knows what you have taken.

If you forget to take DIFICLIR

Take the tablet as soon as you remember, unless it is time for the next dose. In that case, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking DIFICLIR

Do not stop taking DIFICLIR, unless your doctor has advised you to do so.

Keep taking this medicine until the course is finished, even if you feel better.

If you stop taking this medicine too soon, the infection may come back.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

A severe allergic reaction may occur, including trouble breathing (dyspnea), swelling of the face or throat (angioedema), severe rash or severe itching (pruritus) (see section 2). If such reaction occurs, stop taking DIFICLIR and seek medical advice urgently from your doctor, pharmacist or at your local hospital emergency department.

The most **common side effects (may affect up to 1 in 10 people)** are vomiting, nausea and constipation.

Other possible side effects are the following:

Uncommon side effects (may affect up to 1 in 100 people)

- decreased appetite
- dizziness, headache
- dry mouth, altered taste (dysgeusia)
- bloated feeling, wind (flatulence)
- certain blood tests might show changed levels, e.g. increased liver enzymes (alanine aminotransferase)
- rash, itching (pruritus)

Not known side effects (frequency cannot be estimated from the available data)

- swelling of the face and throat (angioedema), trouble breathing (dyspnea)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (for details see below). By reporting side effects, you can help provide more information on the safety of this medicine.

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5. How to store DIFICLIR

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.

Do not throw away any medicines 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.

6. Contents of the pack and other information

What DIFICLIR contains

- The active substance is fidaxomicin. Each film-coated tablet contains 200 mg of fidaxomicin.
- The other ingredients are:
Tablet core: microcrystalline cellulose, pregelatinised starch, hydroxypropyl cellulose, butylated hydroxytoluene, sodium starch glycolate and magnesium stearate
Coating: polyvinyl alcohol, titanium dioxide (E171), talc, polyethylene glycol and lecithin (soy)

What DIFICLIR looks like and contents of the pack

DIFICLIR 200 mg film-coated tablets are capsule shaped tablets, white to off-white in colour, with “FDX” on one side and “200” on the other side.

DIFICLIR is available in:

100 x 1 film-coated tablet in alu/alu perforated unit dose blisters.

20 x 1 film-coated tablet in alu/alu perforated unit dose blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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This leaflet was last revised in 17 May 2018

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>