

**CONSUMER'S LEAFLET IN ACCORDANCE WITH PHARMACISTS REGULATIONS**  
**(5746 – 1986)**

The medication is marketed by a physician's prescription only

**Dificlir**

Coated tablets

**Composition:**

Each Dificlir tablet contains: fidaxomicin 200 mg.

**Excipients** – see section 6 “Additional information”

**Carefully read the entire leaflet before using this medication.**

This leaflet contains concise information about the medication. If you have further questions, contact your doctor or pharmacist.

This medication was prescribed to treat your ailment. Do not pass it to others. It may harm them, even if it seems to you that their disease is similar.

The medication is not intended for children and adolescents weighing less than 12.5 kg.

**1. What is this medication intended for?**

Dificlir is intended for the treatment of adults, adolescents and children aged 6 and above, suffering from colon wall infections caused by a bacterium called *Clostridium difficile*.

**Therapeutic group:** macrolide family of antibiotics.

**2. Before using this medication**

**Do not use the medication if:**

If you are sensitive (allergic) to fidaxomicin or to one of the other ingredients that the medication contains (see section 6).

**Special warnings regarding the use of the medication**

**Before treatment with Dificlir, tell the doctor if:**

- If you are sensitive (allergic) to the family of macrolide antibiotics
- If you have problems with liver or kidney functions
- There is limited information on the use of Dificlir in severe cases of the disease (like pseudomembranous colitis).

**Children and adolescents**

Do not use Dificlir to treat children or adolescents with a body weight of less than 12.5 kg.

**If you are taking, or have recently taken, other medications including non-prescription medications and dietary supplements, tell this to your doctor or pharmacist.**

Dificlir blood levels can be affected by other medicines you take, and blood levels of other medicines can be affected by taking Dificlir. Do not use Dificlir with the following medications without the approval of the primary care physician:

- Cyclosporine

- Ketoconazole
- Erythromycin, Clarithromycin
- Verapamil
- Dronedarone, Amiodarone
- Dabigatran

**Use of the medication and food:** The medication can be taken before, after or during meals.

**Pregnancy and nursing**

If you are pregnant, think you are pregnant, plan to become pregnant or nursing a baby, you should consult the doctor before use.

There is no information regarding possible damage of fidaxomicin to the fetus.

It is unknown whether fidaxomicin passes into breast milk.

**Driving and use of machines:** It is not expected that Dificlir will affect your driving ability or the ability to use machines.

**Important information on part of the medication’s ingredients:**

- the medication contains soy (lecithin).
- the medication contains less than 23 mg of sodium per tablet and is therefore defined as a sodium-free tablet.

**3. How will you use the medication?**

You should always use according to the doctor’s instructions.

You should check with the doctor or pharmacist if you are unsure.

Dosage and manner of treatment will be determined by the doctor only.

The usual dosage for patients with a body weight of 12.5 kg and above is one tablet (200 mg) twice daily (one tablet every 12 hours) for 10 days.

**Do not exceed the recommended dosage.**

**Manner of use:**

- One whole tablet should be swallowed with a glass of water, the tablet must not be chewed or crushed.
- The medication can be taken before, after or during meals.

**If you accidentally have taken a higher dose, or if a child has accidentally swallowed the medication,** proceed immediately to the doctor or to the emergency room of a hospital and bring the medication package with you.

**If you forgot to take the medication,** you should take the dose as soon as you remember; If you remembered to take your dose near the time of taking the next scheduled dose, skip the dose you forgot. Do not take a double dose to make up for a forgotten dose!

**If you stop taking the medication:**

You should continue treatment as recommended by your doctor.

Do not stop taking the medication without doctor’s instructions.

You should continue taking the medication until the end of the course of treatment even if you feel better.

If you stop taking the medication too soon, the infection may return.

Do not take medications in the dark! Check the label and the dose each time you take the medication. Wear glasses if you need them.

If you have further questions about the use of this medication, consult your doctor or pharmacist.

#### **4. Side effects**

As with any medication, the use of Dificlir may cause side effects in some users. Do not be alarmed by reading the list of side effects. It is possible you will not suffer any of them.

Discontinue treatment and contact your doctor immediately in case of:

Severe allergic reaction such as difficulty breathing, swelling of the face or throat, severe rash or itching.

- Common side effects (may appear in up to 1 of 10 patients) are:
  - Vomiting.
  - Nausea.
  - Constipation.
  
- Uncommon side effects (may appear in 1 of 100 patients):
  - Reduced appetite.
  - Dizziness and headaches.
  - Dry mouth, changes in taste.
  - Sense of being bloated and flatulence.
  - Rash and skin itching.
  
- Side effects which prevalence is unknown (it is impossible to evaluate their prevalence based on the existing information):
  - Swelling of face and throat (angioedema).
  - Difficulty breathing.
  
- Additional side effect in children and adolescents:
  - Urticaria

If a side effect occurred, if one of the side effects worsens, or when you experience a side effect that is not mentioned in the insert, you should consult with the doctor.

Side effects can be reported to the Ministry of Health through a link "report of side effects due to medicine treatment" located in the home page of the Ministry of Health website [www.health.gov.il](http://www.health.gov.il) refers to online form for reporting side effects or by accessing the link: <https://sideeffects.health.gov.il/>

#### **5. How to store the medication?**

Prevent poisoning! This medication and any other medication should be kept in a closed place, out of the reach of children and/or babies and thus prevent poisoning.

Do not induce vomiting without an explicit instruction from the doctor.

Do not use this medication after the expiry date (exp.date) which is indicated on the packaging. The expiry date refers to the last day of that month.

Store at a temperature not exceeding 25°C in the original packaging.

#### **6. Additional information**

In addition to the active substances the medication also contains:

In the tablet itself:

Microcrystalline cellulose, Pregelatinised starch, Hydroxypropyl cellulose, Butylated hydroxytoluene, Sodium starch glycolate, Magnesium stearate.

The tablet coating:

Polyvinyl alcohol, Titanium dioxide (E171), Talc, Polyethylene glycol and Lecithin (soy).

**What does the medication look like and what is the contents of the packaging:**

Coated tablets in the form of a capsule, white-cream in color, with writing “FDX” on one side and “200” on the other side.

The tablets come in a blister packaging, and the blisters in cardboard packaging.

**Name of registration owner and his address:**

Tradis Gat Ltd., 32 Shacham St., Petach Tikva.

**Name of manufacturer and his address:**

Tillotts Pharma, Rheinfelden, Switzerland.

Approved in March 2016

Revised in October 2021 according to MOHs guidelines

**Medication registration number in the National Book of Drugs at the Ministry of Health:**

155-60-34282-00

For simplicity and ease of reading, this leaflet was drafted in male language, though this medication is intended for both genders.