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Dificlir (*fidaxomicin*)

An overview of Dificlir and why it is authorised in the EU

What is Dificlir and what is it used for?

Dificlir is a medicine used to treat children and adults with infections of the gut caused by bacteria called *Clostridioides difficile*.

Dificlir contains the active substance fidaxomicin.

How is Dificlir used?

Dificlir is available as tablets (200 mg) or granules for oral suspension (40 mg/ml) and can only be obtained with a prescription.

In adults and children weighing at least 12.5 kg, the recommended dose is 200 mg twice a day (every 12 hours) for 10 days. For children weighing less than 12.5 kg, the dose depends on the bodyweight. For more information about using Dificlir, see the package leaflet or contact your doctor or pharmacist.

How does Dificlir work?

C. difficile are bacteria that are present naturally in the gut and do not cause any problems in healthy people. This is because they are kept under control by other 'good' bacteria which are beneficial to the body and enhance health. However, some antibiotics that are used to treat infections can interfere with the balance and kill the 'good' bacteria in the gut. When this happens, *C. difficile* bacteria can multiply and produce toxins (poisons) which cause illness such as diarrhoea and fever. At this point, a person is said to be infected with *C. difficile*.

The active substance in Dificlir, fidaxomicin, is an antibiotic that belongs to the class of macrocyclic antibiotics. When it is swallowed most of the active substance does not get absorbed into the blood stream but acts locally on *C. difficile* bacteria in the gut. It works by blocking the bacterial enzyme RNA polymerase, which is used to produce the genetic material that the bacteria need to make proteins. This stops the *C. difficile* bacteria from growing and multiplying, thereby reducing the symptoms of the disease.

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What benefits of Dificlir have been shown in studies?

Dificlir was at least as effective as vancomycin (another antibiotic for *C. difficile* infections) in three main studies in patients with mild to moderately severe *C. difficile* infection. The results of two studies involving a total of 1,147 adults showed that 92% of patients taking Dificlir were cured after 10 days compared with 90% of patients taking vancomycin.

In the third study, which involved 148 patients aged from birth to 18 years, 78% of patients taking Dificlir were cured 2 days after the end of treatment, compared with 71% of patients taking vancomycin.

What are the risks associated with Dificlir?

The most common side effects with Dificlir (which may affect up to 1 in 10 people) are nausea (feeling sick), vomiting and constipation. For the full list of side effects and restrictions with Dificlir, see the package leaflet.

Why is Dificlir authorised in the EU?

Dificlir is effective at curing *C. difficile* infections and is generally well tolerated. Its side effects are similar to those of vancomycin by mouth. The European Medicines Agency therefore decided that the benefits of Dificlir are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Dificlir?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Dificlir have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Dificlir are continuously monitored. Side effects reported with Dificlir are carefully evaluated and any necessary action taken to protect patients.

Other information about Dificlir

Dificlir received a marketing authorisation valid throughout the EU on 5 December 2011.

Further information on Dificlir can be found on the Agency's website:
ema.europa.eu/medicines/human/EPAR/dificlir.

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