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EPAR summary for the public

Dificlir

fidaxomicin

This is a summary of the European public assessment report (EPAR) for Dificlir. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Dificlir.

What is Dificlir?

Dificlir is a medicine that contains the active substance fidaxomicin. It is available as tablets (200 mg).

What is Dificlir used for?

Dificlir is used to treat adults with infections of the gut caused by bacteria called *Clostridium difficile*. The medicine can only be obtained with a prescription.

How is Dificlir used?

The recommended dose is one tablet twice a day (every 12 hours) for 10 days.

How does Dificlir work?

C. difficile are bacteria that are present naturally in the gut and do not cause any problems in healthy people. However, some antibiotics that are used to treat infections can interfere with the balance of '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 RNA that the bacteria need to make proteins. This stops the *C. difficile* bacteria from growing and multiplying.

How has Difclir been studied?

The effects of Difclir were first tested in experimental models before being studied in humans.

Difclir has been compared with vancomycin (another antibiotic for *C. difficile* infections) in two main studies involving a total of 1,147 adult patients with mild to moderately severe *C. difficile* infection. The main measure of effectiveness was the number of patients that were cured after 10 days of treatment.

What benefit has Difclir shown during the studies?

Difclir was at least as effective as vancomycin in curing *C. difficile* infection. When looking at the results of the two studies, 92 % of patients on Difclir were cured compared with 90% of patients on vancomycin.

What is the risk associated with Difclir?

The most common side effects with Difclir (seen in between 1 and 10 patients in 100) are nausea (feeling sick), vomiting and constipation. For the full list of all side effects reported with Difclir, see the package leaflet.

Difclir must not be used in people who are hypersensitive (allergic) to fidaxomicin or any of the other ingredients.

Why has Difclir been approved?

The CHMP considered that Difclir was effective in curing *C. difficile* infections and was generally well tolerated with side effects that are similar to vancomycin. The CHMP noted however, that there are uncertainties about the effects of Difclir in certain groups of patients such as those with liver and kidney problems and recommended that further studies in this group should be carried out. The CHMP considered the severity of *C. difficile* infections and the drawbacks of current treatments and concluded that benefits of Difclir are greater than its risks and recommended that it be given marketing authorisation.

Other information about Difclir

The European Commission granted a marketing authorisation valid throughout the European Union for Difclir on 5 December 2011.

The full EPAR for Difclir can be found on the Agency's website: [ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports](http://ema.europa.eu/Find%20medicine/Human%20medicines/European%20Public%20Assessment%20Reports). For more information about treatment with Difclir, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 10-2011.