EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Dificlir

fidaxomicin

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AUTHORISED
This medicine is authorised for use in the European Union.

Overview

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 macrocylic 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.

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.

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.

Dificlir : EPAR - Medicine overview (PDF/109.92 KB)

First published: 19/12/2011
Last updated: 11/03/2020
EMA/31758/2020

Available languages (22)

Dificlir : EPAR - Risk-management-plan summary (PDF/219.06 KB)

First published: 21/01/2019
Last updated: 11/03/2020

More detail is available in the summary of product characteristics

This EPAR was last updated on 24/03/2021

Authorisation details

Product details	
Name	Dificlir
Agency product number	EMEA/H/C/002087
Active substance	fidaxomicin
International non-proprietary name (INN) or common name	fidaxomicin
Therapeutic area (MeSH)	Clostridium Infections
Anatomical therapeutic chemical (ATC) code	A07AA12

Publication details	
Marketing-authorisation holder	Tillotts Pharma GmbH
Revision	14
Date of issue of marketing authorisation valid throughout the European Union	05/12/2011

Publication details

Contact address	Warmbacher Strasse 80 79618 Rheinfelden Germany

Product information

09/03/2021 Dificlir - EMEA/H/C/002087 - T/0044

Dificlir : EPAR - Product Information (PDF/246.11 KB)

First published: 19/12/2011
Last updated: 24/03/2021

Available languages (24)

Contents

- Annex I - Summary of product characteristics
- Annex IIA - Manufacturing-authorisation holder responsible for batch release
- Annex IIB - Conditions of the marketing authorisation
- Annex IIIA - Labelling
- Annex IIIB - Package leaflet

Please note that the size of the above document can exceed 50 pages.

You are therefore advised to be selective about which sections or pages you wish to print.

Dificlir : EPAR - All Authorised presentations (PDF/23.49 KB)

First published: 19/12/2011
Last updated: 11/03/2020

Available languages (24)

Pharmacotherapeutic group

Antidiarrheals, intestinal antiinflammatory / antiinfective agents

Therapeutic indication

Dificlir film-coated tablets is indicated for the treatment of Clostridioides difficile infections (CDI) also known as C. difficile-associated diarrhoea (CDAD) in adult and paediatric patients with a body weight of at least 12.5 kg.

Consideration should be given to official guidelines on the appropriate use of antibacterial agents.

Dificlir granules for oral suspension is indicated for the treatment of Clostridioides difficile infections (CDI) also known as C. difficile-associated diarrhoea (CDAD) in adults and paediatric patients from birth to < 18 years of age.

Consideration should be given to official guidelines on the appropriate use of antibacterial agents.

Assessment history

Changes since initial authorisation of medicine

Dificlir : EPAR - Procedural steps taken and scientific information after authorisation (PDF/213.4 KB)

First published: 23/03/2012
Last updated: 24/03/2021

Dificlir-H-C-002087-X-0034-G : EPAR - Assessment Report - Extension (PDF/1.48 MB)

Adopted

First published: 11/03/2020
EMA/4852/2020

CHMP post-authorisation summary of positive opinion for Dificlir (X-34) (PDF/157.31 KB)

Adopted

First published: 13/12/2019
EMA/CHMP/515208/2019

Dificlir-H-C-2087-P46-0022 : EPAR - Assessment Report (PDF/580.32 KB)

Adopted

First published: 16/02/2015
Last updated: 16/02/2015
EMA/773298/2014

Dificlir-EMEA-H-C-2087-PSUV-0015: EPAR - Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation (PDF/60.89 KB)

First published: 25/04/2014
Last updated: 25/04/2014
EMA/223574/2014

Initial marketing-authorisation documents

Dificlir : EPAR - Public assessment report (PDF/966.4 KB)

Adopted

First published: 19/12/2011
Last updated: 19/12/2011
EMA/857570/2011

CHMP summary of positive opinion for Dificlir (PDF/46.33 KB)

Adopted

First published: 23/09/2011
Last updated: 23/09/2011
EMA/CHMP/724015/2011

News

- Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 9-12 December 2019

  13/12/2019

Related content

- Dificlir: Paediatric investigation plan

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