Brand Name: Dificid Generic: fidaxomicin Type: small molecule

Year Accepted/Phase: 2011

Mechanism:

Fidaxomicin is a macrolide antibiotic that works by inhibiting bacterial RNA synthesis. It binds to the bacterial RNA polymerase, blocking the transcription of essential proteins and ultimately leading to bacterial cell death.

Chemical Structure:

Indication:

Dificid is indicated for the treatment of Clostridioides difficile-associated diarrhea (CDAD) in adults and pediatric patients aged 6 months and older.

Clinical trials:

Clinical Trial for Clostridioides difficile Infection (CDI) – OPT-80-003 (Phase III)

Pubmed: https://pubmed.ncbi.nlm.nih.gov/20446864/

Purpose: Compare the efficacy and safety of fidaxomicin to vancomycin in patients with Clostridioides difficile infection.

Dates: Conducted from 2007 to 2009.

Results: The trial showed that fidaxomicin was non-inferior to vancomycin in achieving clinical cure rates. However, fidaxomicin had a significantly lower rate of recurrence of CDI within 28 days after treatment (15.4% for fidaxomicin vs. 25.3% for vancomycin).

Impact: These results supported the use of fidaxomicin as an effective treatment option for CDI, particularly in reducing recurrence rates.

Clinical Trial for Clostridioides difficile Infection (CDI) – OPT-80-004 (Phase III)

Purpose: Further evaluate the efficacy and safety of fidaxomicin compared to vancomycin in treating CDI.

Dates: Conducted from 2008 to 2010.

Results: The study confirmed the findings of the previous trial, with fidaxomicin demonstrating similar clinical cure rates to vancomycin and a significantly lower recurrence rate (12.7% for fidaxomicin vs. 26.9% for vancomycin).

Impact: The consistent results from this trial reinforced fidaxomicin's role in CDI treatment, particularly in reducing recurrence rates, which is crucial for patient outcomes.

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