

AMBER GUIDANCE FOR FIDAXOMICIN

1. Background

Fidaxomicin is an antibiotic belonging to the macrocyclic class of antibacterials. It has a narrow spectrum of antimicrobial activity against most clostridial spp, including *Clostridioides difficile*, against which it is bactericidal. Fidaxomicin has limited activity against normal gut flora. It has minimal absorption from the intestinal tract and thus its bacterial action is through a topical effect on the gut. It has no activity in systemic infections.

2. Indication

Fidaxomicin is licensed in adults for the treatment of *Clostridioides difficile* infections (CDI).

In Hull, East Riding of Yorkshire, North East Lincolnshire and North Lincolnshire areas Fidaxomicin is a restricted antibiotic. Use should be reserved for the treatment of CDI as recommended in antimicrobial guidance, prescribed by or recommended by a Consultant Microbiologist or Consultant in Infectious Disease.

3. Dose/Duration

200mg twice daily (12 hourly) for 10 days

4. Contraindications

Avoid use in pregnancy and breast feeding.

No information available for use in severe renal impairment (eGFR < 30ml/minute/1.73m²) and moderate to severe hepatic impairment - use with caution.

Some patients with hypersensitivity reactions reported a history of allergy to macrolides. Fidaxomicin should be used with caution in patients with a known macrolides allergy.

5. Adverse effects

Adverse effects	Action for GP
Nausea, vomiting, constipation	Usually self-limiting.

6. Drug interactions

The following drugs are known or suspected interactions:	
Interacting Drug	Advice
P-gp inhibitors including Amiodarone, Ciclosporin, Clarithromycin, Dronedarone, Erythromycin, Ketoconazole & Verapamil	Not recommended.
P-gp substrates e.g. dabigatran	Use with caution possible increase in dabigatran levels.

7. Pregnancy and Lactation

Avoid use in pregnancy or lactation due to lack of data.

8. Information for patient

Patients should be informed of risks and benefits of treatment and importance of completing course.

9. Contacts

Hull University Teaching Hospitals Trust. 01482 875875. Ask for Infection consultant on call (may be a microbiologist or infectious disease consultant)

York Teaching Hospitals Foundation Trust. 01904 725856. Ask for Microbiologist on call.

NLAG Foundation Trust. 03033 306999. For results, extension 306610. For advice extension 306999

Document and version control	This information is not inclusive of all prescribing information and potential adverse effects. Please refer to the SPC (data sheet) or BNF for further prescribing information.		
	Version number:	1	
	Consultation	Shilpa Jethwa - Consultant Pharmacist -NLAG, ACAT HUTH (2020 HERPC version)	
	Date approved by Guidelines and SCF Group:	18/1/2023	
	Date approved by APC:	1/2/2023	
	Review date:	Feb 2026	
Version number	Author	Job title	Revision description:
1	Jane Morgan/Lorraine Cullen	Principal Pharmacists - HUTH	Adapted from HERPC guidance