

Guideline for Prescribing of 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 *Clostridium 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 *Clostridium difficile* infections (CDI).

In Hull and East Yorkshire area Fidaxomicin is a restricted antibiotic. Use should be reserved for the treatment of recurrent CDI, 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 / CAUTIONS

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.

Drug interactions

Avoid with P-gp inhibitors including Amiodarone, Ciclosporin, Clarithromycin, Dronedarone, Erythromycin, Ketoconazole & Verapamil.

Manufacturers also report possible interaction with dabigatran – no clinical evidence available – use with caution.

5. ADVERSE EFFECTS

Common side effects (≥1/100 to <1/10) - nausea, vomiting, constipation.

Fidaxomicin is an intensively monitored drug as such any possible adverse effects (including any considered not to be serious) relating to treatment should be reported via the yellow card scheme (www.yellowcard.gov.uk).

Details of contraindications, cautions, drug interactions and adverse effects listed above are not exhaustive. For further information always check with BNF www.bnf.org.uk or SPC (www.medicines.org.uk).

6. INFORMATION TO PATIENT

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

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

APPROVAL PROCESS

Written by:	Marie Miller, Interface Pharmacist
Reviewed by:	Lorraine Cullen, Lead Pharmacist – Infection, HUTH (01/20)
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Ratified by:	HERPC Nov 16. Updated Jan 20
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