



ANTIMICROBIAL SAFETY SUMMARY FOR COMMUNITY-BASED HEALTHCARE PROFESSIONALS - Fidaxomicin ADULT

INDICATION:

For the treatment of *Clostridioides difficile* infection (CDI). In the community setting, fidaxomicin should only be initiated on the recommendation of a Consultant Microbiologist or Infectious Diseases Physician. In general, severe cases of CDI are managed in hospital.

USUAL TREATMENT REGIMEN:

200 mg every 12 hours for 10 days.

Fidaxomicin is available as film-coated tablets (200mg) or as granules for oral suspension (40mg/ml). Fidaxomicin can be taken with or without food. Tablets should be swallowed whole with water.

CONTRAINDICATIONS:

Hypersensitivity to fidaxomicin or any excipients

CAUTIONS:

- Hypersensitivity reactions including angioedema - stop treatment if allergic reaction occurs. Caution prescribing in patients with a history of macrolide allergy due to reports of cross allergy
- Pseudomembranous colitis, fulminant or life-threatening CDI: limited clinical data - use with caution
- Pregnancy and breastfeeding: limited data therefore use not recommended in pregnancy and risk benefit analysis should be carried out to assess continuation of breastfeeding versus administration of fidaxomicin

CONCOMITANT MEDICATION

- As part of the management of a person with *C. difficile* infection, laxatives should be discontinued and anti-motility agents are not advised. Consideration should be given to the discontinuation of concomitant antibiotics and proton pump inhibitors if deemed appropriate by the clinician.
- Drug-drug interactions:
Co-administration with potent P-glycoprotein inhibitors e.g. ketoconazole, cyclosporine, erythromycin, clarithromycin, azithromycin, ranolazine, verapamil, dronedarone, amiodarone is not recommended
P-glycoprotein substrates: A significant interaction with dabigatran cannot be excluded. Until more is known, patients should be monitored for signs and symptoms of bleeding.

POTENTIAL SIDE EFFECTS:

- Common ($\geq 1/100$ to $< 1/10$): nausea (2.7%), vomiting (1.2%), and constipation (1.2%)
- Uncommon ($\geq 1/1000$ to $< 1/100$): rash, pruritus, decreased appetite, dizziness, headache, dysgeusia, abdominal distention, flatulence, dry mouth
- Frequency Unknown: hypersensitivity reactions (angioedema, dyspnea)

SAFETY IN SPECIFIC PATIENT COHORTS:

RENAL IMPAIRMENT: No dose adjustment required. Use with caution in patients with severe renal impairment due to limited clinical data.

HEPATIC IMPAIRMENT: No dose adjustment required. Use with caution in patients with moderate to severe hepatic impairment due to limited clinical data

AVAILABLE PRODUCTS:

Fidaxomicin is only available in community pharmacy through the High Tech Arrangements. A GP may prescribe fidaxomicin, but must state the name and base hospital of the consulting Consultant Microbiologist or Infectious Diseases Physician on the prescription in order for the community pharmacy to process through the High Tech Arrangements.

Further information can be found on the summary of product characteristics (SmPC) on www.hpra.ie

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