Tillotts Pharma UK Ltd
The Larbourne Suite
8 The Stables
Wellingore
Lincolnshire
LN5 0HX

January 2024

Dear Healthcare Professional,

Re: Emergency ordering service for fidaxomicin 200mg tablets and fidaxomicin 40mg/ml for oral suspension

Product	Pack size	PIP Code	NHS price (£)
Fidaxomicin 200mg film-coated tablets	20	3709375	£1350
Fidaxomicin 40 mg/ml granules for oral suspension	1	4214284	£1350

Fidaxomicin tablets and fidaxomicin granules for oral suspension are available to order via Alliance Healthcare. Alliance Healthcare offer twice daily delivery Monday to Friday, and morning delivery on a Saturday.

In the event that fidaxomicin is required more urgently than would be supplied through your standard service, an emergency ordering service is available. To access this, please call Alliance customer service on **0330 100 0449** and enter your Alliance account number when prompted. You will be directed to the out of hours security company who will transfer your call to your local Alliance service centre. Alliance will arrange a courier to deliver the medication within 12 hours. You will not be charged for using this emergency ordering service.

Should you have any difficulties in obtaining fidaxomicin, please contact Tillotts Commercial Team on ukcommercial@tillotts.com or call 07387 016169.

Kind regards,

K. Glover

Katherine Glover
Supply Chain and Regulatory Manager
Tillotts Pharma UK Ltd

Fidaxomicin 200 mg film-coated tablets & 40 mg/ml granules for oral suspension - Prescribing Information

For full prescribing information, please refer to the Summary of Product Characteristics (SPC).
Presentation: *Film-coated tablets* containing 200 mg fidaxomicin. *Granules for oral suspension*, each ml of oral suspension contains 40 mg of fidaxomicin when reconstituted with water.
Indications: Treatment of *Clostridioides difficile* infections (CDI), also known as *C. difficile* associated diarrhoea (CDAD), in adults and paediatric patients with a bodyweight of at least 12.5kg (*film-coated tablets*), in adults and paediatric patients from birth to < 18 years of age (*granules for oral suspension*). Consideration should be given to official guidelines on the appropriate use of antibacterial agents.
Posology and method of administration: *Film-coated tablets: Adults and elderly (≥65 years of age): Standard dosing;* The recommended dose is 200 mg (one tablet) administered twice daily (once every 12 hours) for 10 days. *Extended-pulsed dosing;* Fidaxomicin 200 mg tablets should be administered twice daily for days 1-5 (no intake of a tablet on day 6) then once daily on alternate days for days 7-25. If a dose has been forgotten, the missed dose should be taken as soon as possible or, if it's nearly time for the next dose, the tablet should be skipped altogether. Special populations: *Renal impairment:* Use with caution in patients with severe renal impairment. *Hepatic impairment:* Use with caution in patients with moderate to severe hepatic impairment. *Paediatric population:* The recommended dose in paediatric patients weighing at least 12.5 kg is 200 mg administered twice daily (once every 12 hours) for 10 days. Fidaxomicin is intended for oral use. Tablets should be swallowed whole with water and can be taken with or without food. *Granules for oral suspension: Adults: Standard dosing*; The recommended dose is 200 mg (5 ml) administered twice daily (once every 12 hours) for 10 days. *Extended-pulsed dosing*; FIDAXOMICIN 40 mg/ml granules for oral suspension (5 ml) should be administered twice daily for days 1-5 (no intake of suspension on day 6) then once daily on alternate days for days 7-25. If a dose has been forgotten, the missed dose should be taken as soon as possible or, if it's nearly time for the next dose, the dose should be skipped altogether. Special populations: Renal impairment: Use with caution in patients with severe renal impairment. Hepatic impairment: Use with caution in patients with moderate to severe hepatic impairment. *Paediatric population:* For appropriate dosing in the paediatric population, granules for oral suspension or film-coated tablets may be used. The recommended dose in paediatric patients weighing at least 12.5 kg is 200 mg (5ml oral suspension) administered twice daily (once every 12 hours) for 10 days. The recommended dose of the oral suspension in paediatric patients, by body weight, to be administered twice daily (once every 12 hours) for 10 days, is presented in tabular format in the SPC. Fidaxomicin is intended for oral use by ingestion or via an enteral feeding tube using a syringe, if necessary. The oral suspension can be taken with or without food. Instructions for reconstitution and administration are provided in the SPC.
Contraindications: Hypersensitivity to the active substance or to any of the excipients.
Special warnings and precautions for use: Hypersensitivity reactions including severe angioedema have been reported. If a severe allergic reaction occurs during treatment with fidaxomicin, the medicinal product should be discontinued and appropriate measures taken. Use with caution in patients with a known macrolides allergy. Use with caution in patients with severe renal impairment or moderate to severe hepatic impairment. Use with caution in patients with pseudomembranous colitis, fulminant or life threatening CDI. Co-administration of potent P-glycoprotein (p-gp) inhibitors such as cyclosporine, ketoconazole, erythromycin, clarithromycin, verapamil, dronedarone and amiodarone is not recommended. *Granules for oral suspension only*: Contains <1mmol sodium per 5ml suspension, and are essentially sodium free. Only one paediatric patient below 6 months of age and no patients with a body weight below 4kg have been exposed to fidaxomicin in clinical trials therefore, fidaxomicin should be used with caution in these patients. Testing for *C. difficile* colonisation or toxin is not recommended in children <1yr due to high rate of asymptomatic colonisation unless severe diarrhoea is present in infants with risk factors for stasis. Contains sodium benzoate, which may increase jaundice in newborn babies.
Interactions: Fidaxomicin is a substrate of P-gp and co-administration of single doses of the P-gp inhibitor cyclosporine A and fidaxomicin in healthy volunteers, resulted in an increase in the Cmax and AUC of fidaxomicin and its main active metabolite OP 1118. As the clinical relevance of this increase in exposure is unclear, co-administration of potent inhibitors of P-gp, such as cyclosporine, ketoconazole, erythromycin, clarithromycin, verapamil, dronedarone and amiodarone is not recommended. Fidaxomicin may be a mild to moderate inhibitor of intestinal P-gp. Fidaxomicin (200 mg twice daily) had a small but not clinically relevant effect on digoxin exposure. However, a larger effect on P-gp substrates with lower bioavailability more sensitive to intestinal P-gp inhibition such as dabigatran etexilat cannot be excluded. Fidaxomicin has no clinically significant effect on the exposure of rosuvastatin. Interaction studies have only been performed in adults.

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Fertility, pregnancy and lactation: There are no data available from the use of fidaxomicin in pregnant women. It is preferable to avoid the use of fidaxomicin during pregnancy. It is unknown whether fidaxomicin and its metabolites are excreted in human milk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from fidaxomicin therapy, taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. Fidaxomicin had no effects on fertility when evaluated in rats.
Undesirable effects: *Common:* vomiting, nausea, constipation. *Uncommon:* rash, pruritus, decreased appetite, dizziness, headache, dysgeusia, abdominal distention, flatulence, dry mouth. *Not known:* hypersensitivity reactions (angioedema, dyspnea). *Description of selected adverse reactions:* Acute hypersensitivity reactions, such as angioedema and dyspnea, have been reported during post-marketing. The safety and efficacy of fidaxomicin was evaluated in 136 patients from birth to less than 18 years of age. Frequency, type and severity of adverse reactions in children are expected to be the same as in adults. In addition to the ADRs shown above, two cases of urticaria were reported.
Package quantities and Basic NHS Cost: *Film-coated tablets*: 200 mg x 20 Tablet: £1,350.00. *Granules for oral suspension*: 1 bottle containing 7.7g granules: £1,350.00.
Legal Classification: POM.
Marketing Authorisation numbers: *Film-coated tablets*: PLGB 36633/0015 (GB) and EU/1/11/733/003-004 (NI). *Granules for oral suspension*: PLGB 36633/0016 (GB) and EU/1/11/733/005 (NI).
Marketing Authorisation Holder: Tillotts Pharma UK Ltd, The Larbourne Suite, The Stables, Wellingore Hall, Wellingore, Lincolnshire, LN5 0HX, UK.

Date of Preparation of Prescribing Information: April 2024
Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk. Adverse events should also be reported to Tillotts Pharma UK Ltd. (address as above) Tel: 01522 813500.