Package leaflet: Information for the user

FIDAXOMICIN 40 mg/ml granules for oral suspension
fidaxomicin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What FIDAXOMICIN is and what it is used for

FIDAXOMICIN is an antibiotic which contains the active substance fidaxomicin.

FIDAXOMICIN oral suspension is used in adults, adolescents and children from birth to less than 18 years to treat infections of the lining of the colon (large intestine) with certain bacteria called *Clostridioides difficile*. This serious illness can result in painful, severe diarrhoea. FIDAXOMICIN works by killing the bacteria that cause the infection and helps to reduce the associated diarrhoea.

2. What you need to know before you take FIDAXOMICIN

Do not take FIDAXOMICIN
- If you are allergic to fidaxomicin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking FIDAXOMICIN.

If you feel that you might have a severe allergic reaction such as trouble breathing (dyspnea), swelling of the face or throat (angioedema), severe rash, severe itching (pruritus) or severe hives (urticaria), stop taking FIDAXOMICIN and seek medical advice urgently from your doctor, pharmacist or at your local hospital emergency department (see section 4).

If you are allergic to macrolides (a class of antibiotics), ask your doctor for advice before using this medicine. Your doctor will tell you whether this medicine is suitable for you.

If you have kidney or liver problems, ask your doctor for advice before using this medicine. Your doctor will tell you whether this medicine is suitable for you.

There are limited data available on the use of fidaxomicin in severe cases of the disease (e.g. pseudomembranous colitis). Your doctor will know whether your disease falls in the severe categories and will tell you whether this medicine is suitable for you.

Other medicines and FIDAXOMICIN
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

FIDAXOMICIN blood levels can be affected by other medicines you take, and blood levels of other medicines can be affected by taking FIDAXOMICIN. Examples of such medicines are:
- cyclosporin (a medicine used to dampen down the body's immune reactions, used e.g. after an organ or bone marrow transplant, for psoriasis or eczema, or for rheumatoid arthritis or nephrotic syndrome)
- ketoconazole (a medicine used to treat fungal infections)
- erythromycin (a medicine used to treat ear, nose, throat, chest and skin infections)
- clarithromycin (a medicine used to treat chest infections, throat and sinus infections, skin and tissue infections and *Helicobacter pylori* infections associated with duodenal or stomach ulcer)
- verapamil (a medicine used to treat high blood pressure or to prevent chest pain attacks, or used following a heart attack to prevent another one)
- dronedarone and amiodarone (medicines used to control the heartbeat)
- dabigatran etexilat (a medicine used to prevent the formation of blood clots after hip or knee replacement surgery)

You should not use FIDAXOMICIN in combination with one of these medicines, unless your doctor tells you otherwise. If you use one of these medicines, please ask your doctor for advice before taking this medicine.

Pregnancy and breast-feeding
You should not take FIDAXOMICIN if you are pregnant, unless your doctor tells you otherwise.
This is because it is not known whether fidaxomicin can harm your baby.
If you are pregnant or think you may be pregnant, ask your doctor or pharmacist for advice before taking this medicine.

It is not known whether fidaxomicin passes into breast milk, but it is not expected to do so.
If you are breastfeeding ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
FIDAXOMICIN is not expected to affect your ability to drive, use tools or machines.

FIDAXOMICIN contains sodium benzoate (E211)
This medicine contains 2.5 mg sodium benzoate (E 211) in each ml oral suspension. Sodium benzoate (E 211) may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

FIDAXOMICIN contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per 5 ml suspension, that is to say essentially 'sodium-free'.

3. How to take FIDAXOMICIN

Always take this medicine exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will determine your dose depending on your weight.

The standard dosing for patients weighing at least 12.5 kg is 200 mg (5 ml oral suspension) administered twice daily (once every 12 hours) for 10 days. (see scheme 1 below).

It is possible that your doctor has prescribed an alternate dosing. The recommendation for an alternate dosing is twice daily administration for days 1-5. Do not take any dose on day 6, then once daily every other day for the days 7-25 (see also scheme 2 below).

Scheme 1 - Standard dosing

DAY	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Morning	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml
Evening	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml

Scheme 2 - Alternate dosing

DAY	1	2	3	4	5					
Morning	5 ml	5 ml	5 ml	5 ml	5 ml					
Evening	5 ml	5 ml	5 ml	5 ml	5 ml					
DAY	6	7	8	9	10	11	12	13	14	15
	-	5 ml	-	5 ml	-	5 ml	-	5 ml	-	5 ml
DAY	16	17	18	19	20	21	22	23	24	25
	-	5 ml	-	5 ml	-	5 ml	-	5 ml	-	5 ml

5 ml - Fidaxomicin 40 mg/ml granules for oral suspension

- No medicine

Another form of this medicine (tablets) may be more suitable for adults and older children (e.g. adolescents); ask your doctor or pharmacist.

The recommended dose for children by body weight is as follows:

Weight band of patient	**Mg per dose (every 12 hours)**	**Volume of fidaxomicin oral suspension (every 12 hours)**
< 4.0 kg	40 mg	1 ml
4.0 - < 7.0 kg	80 mg	2 ml
7.0 - < 9.0 kg	120 mg	3 ml
9.0 - < 12.5 kg	160 mg	4 ml
≥ 12.5 kg	200 mg	5 ml

You can take FIDAXOMICIN before, during or after meals.

How to take the FIDAXOMICIN dose using an oral syringe

Your pharmacist or heatlthcare professional will prepare FIDAXOMICIN oral suspension before giving it to you. If the product is not provided to you as a suspension, please contact your pharmacist or healthcare professional.

Instructions for use:
Use the oral syringe and adaptor provided by the pharmacist or healthcare professional to make sure you measure the right amount. If an oral syringe and adaptor has not been provided to you, please contact your pharmacist or healthcare professional.
Your pharmacist will advise you how to measure the medicine using the oral syringe. Please see instructions below before using FIDAXOMICIN suspension.

1. Take the bottle from the refrigerator 15 minutes prior to administration.
2. After 15 minutes, shake the bottle gently 10 times and let the bottle stand for 1 minute.
3. Verify if the liquid is smooth and not lumpy (i.e. homogenous).
4. Remove the cap and attach the adaptor to the bottle according to the instructions by your pharmacist or healthcare professional.
5. Insert the tip of the oral syringe into the adaptor until it is firmly in place.

6. Invert the bottle 3 times and turn the bottle upside down, so the syringe is on the bottom.
7. Pull back the plunger of the oral syringe to withdraw the amount prescribed by your doctor from the inverted bottle.
8. Leave the syringe in place and turn the bottle upright, ensuring the plunger does not move. Gently remove the syringe from the adaptor and confirm the appropriate dose has been measured.
9. Slowly dispense the oral suspension directly into the patient's mouth until all of the liquid medicine is given.
10. If you have been given a press-in adaptor, leave the bottle adaptor in the neck of the bottle or follow the instructions by your pharmacist or healthcare professional.
11. After administration, store the remaining suspension in a refigerator.
12. To allow reuse of the oral syringe, flush the syringe with warm drinking water (3 times minimally) or until clear water comes out of the syringe. Dry external surfaces and internal surfaces as much as possible. Leave to dry until further use.

If you started using this product in a hospital, your pharmacist or healthcare professional will provide you with the suspension, oral syringe and adaptor at your discharge.

If you take more FIDAXOMICIN than you should
If you have taken more of the oral suspension than you should have, talk to a doctor. Take the medicine pack with you so the doctor knows what you have taken.

If you forget to take FIDAXOMICIN
Take the oral suspension as soon as you remember, unless it is time for the next dose. In that case, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking FIDAXOMICIN
Do not stop taking FIDAXOMICIN, unless your doctor has advised you to do so.
Keep taking this medicine until the course is finished, even if you feel better.
If you stop taking this medicine too soon, the infection may come back.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

A severe allergic reaction may occur, including trouble breathing (dyspnea), swelling of the face or throat (angioedema), severe rash or severe itching (pruritus) (see section 2). If such reaction occurs, stop taking FIDAXOMICIN and seek medical advice urgently from your doctor, pharmacist or at your local hospital emergency department.

The most **common** side effects (may affect up to 1 in 10 people) are:
- vomiting
- nausea
- constipation.

Other possible side effects are the following:
Uncommon side effects (may affect up to 1 in 100 people)
- decreased appetite
- dizziness, headache
- dry mouth, altered taste (dysgeusia)
- bloated feeling, wind (flatulence)
- rash, itching (pruritus)

Not known side effects (frequency cannot be estimated from the available data)

– swelling of the face and throat (angioedema), trouble breathing (dyspnea)

Additional side effects in children and adolescents
– hives

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store FIDAXOMICIN

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after "EXP". The expiry date refers to the last day of that month.

FIDAXOMICIN will be supplied to you as a suspension, which can be stored for up to 27 days. Store in a refrigerator (2°C - 8°C). Do not use the suspension after the expiry date which is written on the bottle label.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What FIDAXOMICIN contains
– The active substance is fidaxomicin.
– The other ingredients are: microcrystalline cellulose, sodium starch glycolate, xanthan gum, citric acid, sodium citrate, sodium benzoate (see section 2), sucralose and mixed berry flavour

What FIDAXOMICIN looks like and contents of the pack
FIDAXOMICIN is presented in an amber glass bottle as white to yellowish white granules for oral suspension. FIDAXOMICIN will be supplied to you as a suspension by your pharmacist or healthcare professional, which will appear as white to yellowish white suspension.
The pack does not contain the oral syringe and adaptor for use with this product. These will be provided to you by your pharmacist or other healthcare professional.

FIDAXOMICIN is also available in the form of film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Tillotts Pharma UK Ltd
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Lincolnshire, LN5 0HX, UK
Tel: + 44 (0) 1522 813500
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Manufacturer
Almac Pharma Services Limited
Seagoe Industrial Estate, Portadown, Craigavon,

BT63 5UA,
United Kingdom

Tillotts Pharma GmbH
Warmbacher Strasse 80
79618 Rheinfelden
Germany

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The following information is intended for healthcare professionals only:

Instructions for reconstitution:

1. Shake the glass bottle to ensure the granules move around freely and no caking of the granules has occurred.
2. Measure 105 ml of purified water and add to the glass bottle. Note that the stability of fidaxomicin granules suspended in mineral water, tap water, or other liquids has not been established.
3. Close the glass bottle and shake vigorously for at least 1 minute.
4. Verify that the resulting liquid has no remaining caked granules left at the bottom of the bottle or any lumps. If caked granules or any lumps are observed, shake the glass bottle vigorously again for at least 1 minute.
5. Let the bottle stand for 1 minute.
6. Verify if a homogenous suspension is obtained.
7. Write the date of expiration of the reconstituted suspension on the bottle label (the shelf-life of the reconstituted suspension is 27 days).
8. Store the bottle at refrigerated temperature (2-8°C) before and during use.
9. Select an appropriate oral syringe and bottle adaptor suitable for dispensing liquid medicinal product to measure the correct dose.

After reconstitution, the suspension (110 ml) will appear as white to yellowish white.

An appropriate commercially available oral syringe and adaptor suitable for dispensing of liquid medicines should be selected by the healthcare professional in order to allow the patient or caregiver to measure the correct dose. The adaptor should be suitable for use in combination with the selected oral syringe and fits the bottle neck size, for example a press-in bottles adaptor (27 mm) or universal bottle adapter.

In case the treatment with fidaxomicin started in a hospital setting and the patient is discharged before the end of the treatment at the hospital, the patient should be provided with the oral suspension and a suitable oral syringe and adaptor. Patients or caregivers should not prepare the oral suspension at home.

Recommended oral syringe capacity for measuring the dose of the oral suspension is presented in the table below.

Suggested oral syringe capacity for accurate dispensing

Prescribed dosing volume	Recommended oral syringe capacity
1 ml	1 ml oral syringe
2 – 5 ml	5 ml oral syringe

If possible, the graduation corresponding to the appropriate dose should be marked or highlighted (according to the dosing table in section 3) on the oral syringe.

Administration via an enteral feeding tube:
In case of administration using an enteral feeding tube, an appropriate commercially available tube should be selected by the healthcare professional. Enteral feeding tubes made of polyvinylchloride (PVC) and polyurethane (PUR) have been shown compatible with the oral suspension. The recommended enteral feeding tube size and flush volume of water are provided in the table below.

Recommended enteral feeding tube size and flush volume

Recommended tube size (diameter)	Recommended flush volume*
4 Fr	at least 1 mL
5 Fr	at least 2 mL
6 – 7 Fr	at least 3 mL
8 Fr	at least 4 mL

* Based on tubes of 120 cm