

Package leaflet: Information for the user

Fidaxomicin SUN 200 mg film-coated tablets 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 {National completed name} is and what it is used for
2. What you need to know before you take {National completed name}
3. How to take {National completed name}
4. Possible side effects
5. How to store {National completed name}
6. Contents of the pack and other information

1. What {National completed name} is and what it is used for

{National completed name} is an antibiotic which contains the active substance fidaxomicin.

{National completed name} film-coated tablets are used in adults, adolescents and children with a body weight of at least 12.5 kg 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. {National completed name} 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 {National completed name}

Do not take {National completed name}

- If you are allergic to fidaxomicin or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to peanut or soya.

Warnings and precautions

Talk to your doctor or pharmacist before taking {National completed name}.

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 {National completed name} 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.

Children and adolescents

Do not give this medicine to children with a body weight below 12.5 kg, because these children require a reduced dose. For appropriate dosing in these patients, fidaxomicin medicinal products formulated as granules for oral suspension may be used.

Other medicines and {National completed name}

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

{National completed name} blood levels can be affected by other medicines you take, and blood levels of other medicines can be affected by taking {National completed name}. 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 {National completed name} 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 {National completed name} 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

{National completed name} is not expected to affect your ability to drive, use tools or machines.

{National completed name} contains sodium

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

3. How to take {National completed name}

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.

The standard dosing for patients weighing at least 12.5 kg is one tablet (200 mg) twice daily (one tablet 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 a tablet 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	200 mg	200 mg	200 mg	200 mg	200 mg	200 mg	200 mg	200 mg	200 mg	200 mg
Evening	200 mg	200 mg	200 mg	200 mg	200 mg	200 mg	200 mg	200 mg	200 mg	200 mg

Scheme 2 - Alternate dosing

DAY	1	2	3	4	5					
Morning	200 mg	200 mg	200 mg	200 mg	200 mg					
Evening	200 mg	200 mg	200 mg	200 mg	200 mg					
DAY	6	7	8	9	10	11	12	13	14	15
	-	200 mg	-	200 mg	-	200 mg	-	200 mg	-	200 mg
DAY	16	17	18	19	20	21	22	23	24	25
	-	200 mg	-	200 mg	-	200 mg	-	200 mg	-	200 mg

200 mg - {National completed name} 200 mg film-coated tablet

- No tablet

Swallow the tablets whole with a glass of water. You can take {National completed name} before, during or after meals.

Fidaxomicin medicinal products formulated as granules for oral suspension may be used in patients with difficulties in swallowing tablets

If you take more {National completed name} than you should

If you have taken more tablets 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 {National completed name}

Take the tablet 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 {National completed name}

Do not stop taking {National completed name}, 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 {National completed name} 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system](#) listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store {National completed name}

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.

This medicinal product does not require any special storage conditions.

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 {National completed name} contains

- The active substance is fidaxomicin. Each film-coated tablet contains 200 mg of fidaxomicin.
- The other ingredients are:
Tablet core: microcrystalline cellulose, pregelatinised starch, hydroxypropyl cellulose, butylhydroxytoluene, sodium starch glycolate and magnesium stearate
Coating: polyvinyl alcohol, talc, titanium dioxide (E171), macrogol and lecithin (soya)

What {National completed name} looks like and contents of the pack

{National completed name} 200 mg film-coated tablets are white to off-white biconvex capsule shaped film coated tablets, approximately 14 mm in length and 6 mm in width, debossed with “S21” on one side and plain on other side.

{National completed name} is available in:

20 film-coated tablets in OPA/Aluminium/PVC/Aluminium blister and 20 x 1 film-coated tablet in OPA/Aluminium/PVC/Aluminium perforated unit dose blister.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This leaflet was last revised in 2026-06-03