



PACKAGE LEAFLET: INFORMATION FOR THE USER

XIFAXANTA ® 200 mg film-coated tablets Rifaximin

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 Xifaxanta 200 mg film-coated tablets are and what they are used for
2. What you need to know before you take Xifaxanta 200 mg film-coated tablets
3. How to take Xifaxanta 200 mg film-coated tablets
4. Possible side effects
5. How to store Xifaxanta 200 mg film-coated tablets
6. Contents of the pack and other information

1. WHAT XIFAXANTA 200 MG FILM-COATED TABLETS ARE AND WHAT THEY ARE USED FOR

XIFAXANTA 200 mg film-coated tablets contain the active substance Rifaximin, an intestinal antibiotic used to treat:

- traveller's diarrhoea in adults when the diarrhoea is not accompanied by fever or blood in the stools, or 8 or more unformed (soft or liquid) stools in the last 24 hours.
- Xifaxanta 200 mg film-coated tablets are not recommended for use in children (aged less than 18 years).

You must talk to a doctor if you do not feel better or if you feel worse after 3 days



2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE XIFAXANTA 200 MG FILM-COATED TABLETS

Do not take Xifaxanta 200 mg film-coated tablets

- if you are allergic (hypersensitive) to rifaximin, to similar types of antibiotics (such as rifampicin or rifabutin) or to any of the other ingredients of this medicine (listed in section 6)
- if you have a fever;
- if you have blood in your stools;
- if you passed 8 or more unformed stools in the last 24 hours.
- if you have constipation, abdominal pain and vomiting caused by blockage of the bowel

Warning and Precautions

Talk to your doctor or pharmacist before taking Xifaxanta 200mg film coated tablets and take special care;

- if, after 3 days of treatment, your symptoms continue or re-appear shortly afterwards do **not** take a second course of Xifaxanta 200 mg film-coated tablets, see a doctor if your symptoms get worse during treatment stop taking Xifaxanta 200 mg film-coated tablets and consult a doctor.

Other medicines and Xifaxanta 200mg film coated tablets

Please tell your doctor or pharmacist if you are taking , have recently taken or might take any other medicines, including medicines obtained without a prescription.

Please tell your doctor if you are taking ciclosporin (a medicine to suppress the body's immune system), warfarin (medicine to prevent blood clotting) or oral contraceptives (medicines to prevent pregnancy).

If you are using activated charcoal (for example to treat wind or diarrhoea) please take Xifaxanta 200 mg film-coated tablets at least 2 hours after taking charcoal.

Xifaxanta 200 mg film-coated tablets with food and drink

Xifaxanta 200 mg film-coated tablets can be taken with or without food. Orally with a glass of water.

Taking this medicine may cause a reddish discolouration of your urine



Pregnancy, breast-feeding and fertility

Xifaxanta 200 mg film-coated tablets are **not** recommended during pregnancy or in fertile women not using contraception.

Inform your doctor

- if you are pregnant , think you may be pregnant or are thinking of becoming pregnant
- if you are breast-feeding or planning to start breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Xifaxanta 200 mg film-coated tablets are unlikely to affect your reactions when driving or using machines. If you feel dizzy or drowsy you should not drive or operate machinery

3. HOW TO TAKE XIFAXANTA 200 MG FILM-COATED TABLETS

Always take Xifaxanta 200 mg film-coated tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Unless otherwise prescribed by the doctor, the usual dose is 1 tablet every 8 hours (600 mg/day). You should continue taking Xifaxanta 200 mg film-coated tablets for three days even if your symptoms have improved.
- Unless otherwise prescribed, the duration of the treatment **should not** exceed three days. If your symptoms persist for more than three days please see a doctor.

Do not break or crush the tablets.

If you take more Xifaxanta 200 mg film-coated tablets than you should

If you take more than the recommended number of tablets, please contact a doctor.

If you forget to take Xifaxanta 200 mg film-coated tablets

- take the missed dose as soon as you remember and take the next scheduled dose at its regular time.



If you stop taking Xifaxanta 200 mg film-coated tablets

If you do not complete the three days of treatment recommended, your symptoms may worsen.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Xifaxanta 200 mg film-coated tablets can cause side effects, although not everybody gets them.

If you have any of the following side effects **stop** taking Xifaxanta 200 mg film-coated tablets and seek urgent medical advice immediately. These may be symptoms of a severe allergic reaction:

- rash, hives or itchy skin,
- shortness of breath, wheezing
- heart racing
- swelling of the mouth, face, ankles or any other part of the body,
- extreme tiredness, dizziness or feeling faint

Common (may affect up to 1 in 10 people):

- headache
- wind, abdominal bloating, abdominal pain, constipation, diarrhoea, urgency to empty your bowels, nausea, involuntary and painful or ineffective straining, vomiting
- fever.

Uncommon (may affect up to 1 in 100 people):

- thrush, cold sore, inflammation or infection of the nose and throat
- abnormal test results in white blood cells
- loss of appetite, loss of body fluid (dehydration)
- abnormal dreams, depressed mood, sleeplessness, nervousness
- numbness, migraine, pins and needles, sinus headache, drowsiness
- double vision
- earache, sensation of the room going round (vertigo)
- increased blood pressure,
- hot flushes



- cough, dry throat, blocked nose, sore throat, runny nose
- upper abdominal pain, indigestion, intestinal movement disorder, dry lips, hard stools, blood in the stools, mucus in stools, taste disorders
- blood test results: increased liver enzyme values
- sunburn
- back pain, muscle cramps, muscle weakness, muscle pain, neck pain
- abnormal urine test results: blood in urine, protein in urine, sugar in urine,
- frequent urination, excessive urination
- frequent periods
- chills, cold sweat, increased sweating, flu-like illness, pain.

The following side effects have been reported, however their frequency cannot be estimated from the available data:

- bacterial infections
- abnormal blood tests results (blood not clotting normally and abnormal liver tests)
- allergic reactions to the drug
- skin roughness, skin redness, - skin with little purple-coloured spots.

Treatment with any antibiotic may cause *Clostridium difficile* associated diarrhoea (CDAD).

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE XIFAXANTA 200 MG FILM-COATED TABLETS

Keep out of the sight and reach of children.

Xifaxanta 200 mg film-coated tablets do not require any special storage conditions.

Do not use Xifaxanta 200 mg film-coated tablets after the expiry date which is stated on the carton and the blister. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.



6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Xifaxanta 200 mg film-coated tablets contain

- The active substance is: Rifaximin. Each film-coated tablet contains: 200 mg of Rifaximin. The other ingredients are: *Tablet core*: sodium starch glycolate type A, glycerol distearate, colloidal anhydrous silica, talc, microcrystalline cellulose. *Tablet coating*: hypromellose, titanium dioxide E171, disodium edetate, propylene glycol, red iron oxide E172.

What Xifaxanta 200 mg film-coated tablets look like and contents of the pack

- Xifaxanta 200 mg film-coated tablets are pink circular biconvex coated tablets, with “AW” embossed on one side.
- They are provided in a blister pack containing 9 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Norgine Pharmaceuticals Ltd.
Moorhall Rd,
Harefield,
Middx,
UB9 6NS,
U.K.

Manufacturer:

Alfasigma S.p.A.
Via E. Fermi, 1
65020 Alanno (PE), ITALY

If you need the information on this leaflet in an alternative format, such as large text, please ring Medical Information on 01895 826 606.

This leaflet was last revised in July 2018