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

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 FILMCOATED 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 200 mg film coated tablets.

Take special care:

- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking rifaximin. Serious skin reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported in association with rifaximin treatment. Stop using Xifaxanta 200 mg film-coated tablets and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.
- 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.

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

Other medicines and Xifaxanta 200 mg 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:
Allergic reactions, symptoms may include:
rash, hives or itchy skin, reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These skin rashes can be preceded by fever and flu-like symptoms;
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.
Life-threatening reactions with flu-like symptoms and a painful rash affecting the skin, mouth, eyes and genitals (Stevens-Johnson syndrome).
Life-threatening reactions with flu-like symptoms and blistering on the skin, mouth, eyes and genitals (toxic epidermal necrolysis).

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 *Clostridioides 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 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 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 Limited
ARC Uxbridge, Building 01,
Sanderson Road,
Uxbridge,
UB8 1DH, UK

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

Other sources of information
If you need the information on this leaflet in an alternative format, such as large print, or Braille please ring 0800 198 5000.

This leaflet was last revised in March 2025