

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

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

Xifaxanta 200 mg film-coated tablets are an intestinal antibiotic and are 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).

2. 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 (see section 6) of Xifaxanta film-coated tablets;
- 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;.

Take special care with Xifaxanta 200 mg film-coated tablets

- 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.

Taking other medicines

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

Please tell your doctor if you are taking ciclosporin (immunosuppressor).

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.

Taking Xifaxanta 200 mg film-coated tablets with food and drink

Xifaxanta 200 mg film-coated tablets can be taken with or without food.

Pregnancy and breast-feeding

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 or 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.

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.

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.

Common side effects (1 in 10 - 100 patients):

- Dizziness, headache
- wind, abdominal bloating, abdominal pain, constipation, diarrhoea, urgency to evacuate faeces, nausea, involuntary and painful or ineffective straining, vomiting
- fever.

Uncommon side effects (1 in 100 – 1,000 patients):

- Thrush, cold sore, swollen throat, inflammation or infection of the nose and throat
- abnormal blood test results (increased lymphocytes, increased monocytes, reduced neutrophilic granulocytes)
- 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)
- heart racing
- increased blood pressure, hot flushes
- cough, dry throat, shortness of breath, 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
- increased liver enzyme values (aspartate-aminotransferase)
- rashes, blotchy skin, sunburn
- back pain, muscle cramps, muscle weakness, muscle pain, neck pain
- blood in urine,
- sugar in urine (glycosuria), frequent urination, excessive urination (polyuria), protein in urine,
- frequent periods (polymenorrhoea)
- loss of strength, chills, cold sweat, increased perspiration, flu-like illness, swollen arm, pain

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

- bacterial infections (*Clostridial* infections)
- abnormal blood tests (reduced platelets, liver function tests out of normal range, international normalised ratio abnormalities)
- severe acute reactions to the drug, allergic reactions to the drug
- near fainting
- giant hives
- skin roughness, skin redness, itching, wheals.

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

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

Keep out of the reach and sight 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. FURTHER 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, 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” printed on both sides.
- They are provided in 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:
Alfa Wassermann S.p.A.
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