Package Leaflet: Information for the user

Rifaximin 550mg film-coated tablets

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 Rifaximin 550mg is and what it is used for
2. What you need to know before you use Rifaximin 550mg
3. How to take Rifaximin 550mg
4. Possible side effects
5. How to store Rifaximin 550mg
6. Contents of the pack and other information

1. What Rifaximin 550mg is and what it is used for

Rifaximin 550mg contains the active substance rifaximin. Rifaximin 550mg is an antibiotic that destroys bacteria, which can cause a disease called hepatic encephalopathy (symptoms include agitation, confusion, muscle problems, difficulty in speaking and in some cases coma).

Rifaximin 550mg is used in adults with liver disease to reduce the recurrence of episodes of overt hepatic encephalopathy.

Rifaximin 550mg can either be used alone or more commonly together with medicines containing lactulose (a laxative).

2. What you need to know before you use Rifaximin 550mg

Do not take Rifaximin 550mg:
- if you are allergic to:
  - rifaximin
  - similar types of antibiotics (such as rifampicin or rifabutin)
  - any of the other ingredients of this medicine (listed in section 6).
- if you have a blockage in your intestine

Warnings and precautions
Talk to your doctor or pharmacist before taking Rifaximin 550mg.
If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking rifaximin.
Take special care with rifaximin:
Serious skin reactions including Stevens-Johnson-syndrome and toxic epidermal necrolysis, have been reported in association with rifaximin treatment. Stop using rifaximin and seek medical attention immediately of you notice any of the symptoms related to these serious skin reactions described in section 4.
While you are taking Rifaximin 550mg your urine may turn a reddish colour. This is quite normal. Treatment with any antibiotic including rifaximin may cause severe diarrhoea. This can happen several months after you have finished taking the medicine. If you have severe diarrhoea during or after using Rifaximin 550mg you should stop taking Rifaximin 550mg and contact your doctor immediately.
If your liver problems are severe your doctor will need to observe you carefully.
Rifaximin 550mg contains sodium
This medicine contains less than 1 mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

Children and adolescents
Rifaximin 550mg is not recommended for children and adolescents aged under 18 years. This medicine has not been studied in children and adolescents.
Other medicines and Rifaximin 550mg
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Please tell your doctor if you are taking any of the following medicines:
- antibiotics (medicines to treat infections)
- warfarin (medicine to prevent blood clotting)
- antiepileptics (medicines for the treatment of epilepsy)
- antiarrhythmics (medicines to treat abnormal heart beat)
- ciclosporin (immunosuppressor)
- oral contraceptives

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine. It is not known if Rifaximin 550mg can harm your unborn baby. Rifaximin 550mg is therefore not to be used if you are pregnant. It is not known if rifaximin may be passed to your baby in breast milk. Rifaximin 550mg is therefore not to be used if you are breast-feeding.
Driving and using machines
Rifaximin 550mg does not normally affect the ability to drive and use machines, but may cause dizziness in some patients. If you feel dizzy you should not drive or operate machinery.

3. How to take Rifaximin 550mg

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The recommended dose is 1 tablet twice a day taken with a glass of water. Continue taking Rifaximin 550mg until your doctor tells you to stop.
If you take more Rifaximin 550mg than you should
If you take more than the recommended number of tablets, even if you do not notice any problems, please contact your doctor.

If you forget to take Rifaximin 550mg
Take the next dose at its normal time. Do not take a double dose to make up for a forgotten tablet.
If you stop taking Rifaximin 550mg
Do not stop taking Rifaximin 550mg without talking to your doctor first because your symptoms may return.
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.
Stop using Rifaximin 550mg and seek medical attention immediately if you notice any of the following symptoms:

Uncommon (may affect up to 1 in 100 people):
- If you have bleeding from swollen blood vessels in your throat (oesophageal varices).
- If you have severe diarrhoea during or after using this medicine. This may be due to an infection of the intestine.

Not known (frequency cannot be estimated from the available data):
- 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.
- If you get an allergic reaction, hypersensitivity or angioedema. Symptoms include:
  - swelling of the face, tongue or throat
  - swallowing difficulties
  - hives and breathing difficulties.
- If you have any unexpected or unusual bleeding or bruising. This may be due to a decrease in the platelets in your blood which increases the risk of bleeding.

Other side effects that may occur

Common (may affect up to 1 in 10 people):
- Depressed mood
- Dizziness
- Headache
- Shortness of breath
- Feeling or being sick
- Stomach ache or bloating/swelling
- Diarrhoea
- Accumulation of fluid in the abdominal cavity (ascites)
- Rash or itching
- Muscle cramps
- Joint pain
- Swelling of ankles, feet or fingers

Uncommon (may affect up to 1 in 100 people):
- Yeast infections (such as thrush)
- Urinary infection (such as cystitis)
- Anaemia (reduction in red blood cells which can make the skin pale and cause weakness or breathlessness)
- Loss of appetite
- Hyperkalaemia (high level of potassium in the blood)
- Confusion
- Anxiety
- Feeling sleepy
- Difficulty sleeping
- Feeling unsteady
- Loss of or poor memory
- Loss of concentration
- Reduced sense of touch
- Convulsions (fits)
- Hot flushes
- Fluid around the lungs (pleural effusion)
- Abdominal pain
- Dry mouth
- Muscle pain
- Needing to pass urine more often than usual
- Difficulty or pain passing urine
- Fever
- Oedema (swelling due to too much fluid in the body)
- Falls

Rare (may affect up to 1 in 1,000 people):
- Chest infections including pneumonia
- Cellulitis (inflammation of tissue under skin)
- Upper respiratory tract infections (nose, mouth, throat)
- Rhinitis (inflammation inside the nose)
- Dehydration (body water loss)
- Changes in blood pressure
- Constant breathing problems (such as chronic bronchitis)
- Constipation
- Back pain
- Protein in the urine
- Feeling weak
- Bruising
- Pain following surgery

Not known (frequency cannot be estimated from the available data):
- Fainting or feeling faint
- Skin irritation, eczema (itchy, red, dry skin)
- Reduction in platelets (seen in the blood)
- Changes in the way the liver is working (seen in blood test)
- Changes in blood coagulation (International Normalised Ratio seen in blood test)

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 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 Rifaximin 550mg

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 and the blister after EXP. The expiry date refers to the last day of that month.
Rifaximin 550mg does not require any special storage conditions.

Do not throw away any medicine 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 Rifaximin 550mg contains

The active substance is rifaximin. Each tablet contains 550mg rifaximin.
The other ingredients are:
- Tablet core: Sodium starch glycolate Type A, Glycerol distearate, Colloidal anhydrous silica, Talc, Microcrystalline cellulose.
- Tablet coat: Poly(vinyl alcohol), Titanium dioxide (E171), Talc, Macrogol, Red iron oxide (E172).

What Rifaximin 550mg looks like and contents of the pack

Pink oval curved film-coated tablets marked with “RX” on one side.
Rifaximin 550mg is available in cartons of 14, 28, 42, 56 and 98 tablets.
Not all pack-sizes may be marketed.

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

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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**.**

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