Package leaflet: Information for the user

RIFAXIMIN ALFASIGMA 550 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 RIFAXIMIN ALFASIGMA is and what it is used for

RIFAXIMIN ALFASIGMA contains the active substance rifaximin. Rifaximin 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 ALFASIGMA is used in adults with liver disease to reduce the recurrence of episodes of overt hepatic encephalopathy.

RIFAXIMIN ALFASIGMA can either be used alone or more commonly together with medicines containing lactulose (a laxative).

2. What you need to know before you take RIFAXIMIN ALFASIGMA

Do not take RIFAXIMIN ALFASIGMA:
- 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 ALFASIGMA.

While you are taking RIFAXIMIN ALFASIGMA 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 ALFASIGMA you should stop taking RIFAXIMIN ALFASIGMA and contact your doctor immediately.

If your liver problems are severe your doctor will need to observe you carefully.

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

Children and adolescents
RIFAXIMIN ALFASIGMA 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 ALFASIGMA

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 ALFASIGMA can harm your unborn baby. RIFAXIMIN ALFASIGMA 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 ALFASIGMA is therefore not to be used if you are breast-feeding.

Driving and using machines
RIFAXIMIN ALFASIGMA 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 ALFASIGMA

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 ALFASIGMA until your doctor tells you to stop.

If you take more RIFAXIMIN ALFASIGMA 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 ALFASIGMA
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 ALFASIGMA
Do not stop taking RIFAXIMIN ALFASIGMA 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 taking RIFAXIMIN ALFASIGMA and tell your doctor IMMEDIATELY if you have any of the following side effects:

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)
- 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.

<u>Other side effects that may occur:</u>

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 retention 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Earlsfort Terrace IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store RIFAXIMIN ALFASIGMA

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 ALFASIGMA 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 ALFASIGMA contains

The active substance is rifaximin. Each tablet contains 550 mg rifaximin.
The other ingredients are:

- *Tablet core*: sodium starch glycolate (Type A), glycerol distearate, colloidal anhydrous silica, talc, microcrystalline cellulose.
- *Tablet coat (opadry oy-s-34907)*: hypromellose, titanium dioxide (E171), disodium edetate, propylene glycol, red iron oxide (E172).

What RIFAXIMIN ALFASIGMA looks like and contents of the pack

Pink oval curved film-coated tablets marked with "RX" on one side.

RIFAXIMIN ALFASIGMA is available in cartons of 14, 28, 42, 56 and 98 tablets.

Not all pack-sizes may be marketed.

Marketing Authorisation Holder
ALFASIGMA S.p.A.
Via Ragazzi del '99, n. 5
40133 Bologna (BO)
Italy

Manufacturer
ALFASIGMA S.p.A.
Via E. Fermi 1, 65020 Alanno (PE)
Italy

ALFASIGMA S.p.A.
Via Pontina Km 30,400, 00071 Pomezia (RM)
Italy

This medicinal product is authorised in the Member States of the EEA under the following names:
Refero: Austria, Hungary, Luxembourg, Portugal, Slovakia
Tixteller: Belgium, Germany, Italy, Netherlands, Poland, Romania, Spain
Tixtar: France, Italy, Spain
Rifaximin Alfasigma: Ireland

This leaflet was last revised in March 2021