

Package leaflet: Information for the user

RIFAXIMAX® 200 / 400 / 550 Tablet

Rifaximin Film-coated Tablet 200 mg / 400 mg / 550 mg IP

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 or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

1. What RIFAXIMAX® is and what it is used for

RIFAXIMAX® is a film-coated tablet that contains the active substance Rifaximin, an intestinal antibiotic. contains the active substance rifaximin.

RIFAXIMAX® 200 mg is used for the treatment of infectious 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.

RIFAXIMAX® 400 and 550 mg 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).

RIFAXIMAX® 400 mg is used for the treatment of adults with hepatic encephalopathy.

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

RIFAXIMAX[®] 200 mg film-coated tablets are not recommended for use in children (aged less than 18 years).

RIFAXIMAX[®] can either be used alone or more commonly together with medicines containing lactulose (a laxative).

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 RIFAXIMAX[®]

Do not take RIFAXIMAX[®]:

- 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
- 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

Warnings and precautions

Talk to your doctor or pharmacist before taking RIFAXIMAX[®] 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 RIFAXIMAX[®] film-coated tablets, see a doctor.
- If your symptoms get worse during treatment stop taking RIFAXIMAX[®] and consult a doctor.
- While you are taking RIFAXIMAX[®] 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 RIFAXIMAX[®] you should stop taking Targaxan and contact your doctor immediately.

Other medicines and RIFAXIMAX[®]

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

- Antibiotics (medicines to treat infections),

- Antiepileptics (medicines for the treatment of epilepsy),
- Antiarrhythmics (medicines to treat abnormal heart beat),
- 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 RIFAXIMAX[®] film-coated tablets at least 2 hours after taking charcoal.

RIFAXIMAX[®] with food and drink

RIFAXIMAX[®] 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 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 RIFAXIMAX[®] can harm your unborn baby. RIFAXIMAX[®] 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. RIFAXIMAX[®] is therefore not to be used if you are breast-feeding.

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

RIFAXIMAX[®] 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 use RIFAXIMAX[®]

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

RIFAXIMAX[®] 200 mg

Unless otherwise prescribed by the doctor, the usual dose is 1 tablet every 8 hours (600 mg/day). You should continue taking RIFAXIMAX[®] 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.

RIFAXIMAX[®] 400 mg

400 mg tablet is to be taken every 8 hours or as per the need assessed by treating physician.

RIFAXIMAX® 550 mg

550 mg tablet is to be taken every 8 hours or as per the need assessed by treating physician.

Rifaximin can be taken with or without food

Do not break or crush the tablets.

If you take more RIFAXIMAX® tablets than you should

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

If you forget to take RIFAXIMAX® tablets

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 RIFAXIMAX® 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, this medicine can cause side effects, although not everybody gets them.

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:
 - 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
- 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. Frequency is not known (cannot be estimated from the available data).

Other side effects that may occur

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

- Depressed mood
- Headache

- Dizziness
- Shortness of breath
- Feeling or being sick
- Accumulation of fluid in the abdominal cavity (ascites)
- Rash or itching
- Muscle cramps
- Wind, abdominal bloating, abdominal pain, constipation, diarrhoea, urgency to empty your bowels, nausea, involuntary and painful or ineffective straining, vomiting
- Joint pain
- Swelling of ankles, feet or fingers

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

- Thrush (yeast infections), cold sore, inflammation or infection of the nose and throat
- Abnormal test results in white blood cells
- Anaemia (reduction in red blood cells which can make the skin pale and cause weakness or breathlessness)
- 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, difficulty or pain passing urine, urinary infection (such as cystitis)
- Frequent periods
- Fever, chills, cold sweat, increased sweating, flu-like illness, pain.
- Hyperkalaemia (high level of potassium in the blood)

- Anxiety
- Feeling sleepy
- Feeling unsteady, falls,
- Confusion, loss of or poor memory, loss of concentration, reduced sense of touch, convulsions (fits)
- Fluid around the lungs (pleural effusion), Oedema (swelling due to too much fluid in the body)
- Abdominal pain
- Dry mouth

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:

Website: www.zuventus.co.in and click the tab “Safety Reporting” located on the top right end of the home page.

By reporting side effects, you can help provide more information on the safety of this medicine.

You can also report the side effect with the help of your treating physician.

5. How to store RIFAXIMAX[®]

Keep this medicine out of the sight and reach of children

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment. Keep this medicine out of the sight and reach of children.

6. Contents of the pack and other information

RIFAXIMAX[®] 200

Each film-coated tablet contains:

Rifaximin Ph. Eur. 200 mg

Colours: Sunset Yellow FCF & Titanium Dioxide I.P.

RIFAXIMAX[®] 400

Each film coated tablet contains:

Rifaximin Ph. Eur. 400 mg

Colours: Sunset Yellow FCF & Titanium Dioxide I.P.

RIFAXIMAX[®] 550

Each film coated tablet contains:

Rifaximin Ph. Eur. 550 mg

Colours: Sunset Yellow FCF & Titanium Dioxide I.P.