

PATIENT INFORMATION LEAFLET

COLIDUR FORT 550 mg film coated tablet

It is taken orally.

- **Active ingredient:** Each film-coated tablet contains 550 mg of rifaximin.
- **Excipients:** • Excipients: Contains sodium starch glycolate, microcrystalline cellulose 200, colloidal silicon dioxide, magnesium stearate, glycerol distearate, talc, hypromellose, titanium dioxide, propylene glycol, red iron oxide, disodium EDTA.

Before you start using this medicine, carefully read this INSTRUCTIONS FOR USE, because it contains important information for you.

- *Keep this user manual. You can need to read again.*
- *If you have other questions, please talk your doctor or pharmacist.*
- *This medicine has been prescribed for you personally, do not give it to others.*
- *During the use of this medicine, tell your doctor that you are using this medicine when you go to the doctor or hospital.*
- *Follow exactly what is written in this instruction. Do not use **high or low** doses other than the dose recommended to you about the drug.*

In this Leaflet:

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Headings are included.

1. What COLIDUR FORT is and what it is used for

COLIDUR FORT is presented in blister packs containing 42 pink oval film-coated tablets.

Each film-coated tablet contains 550 mg of rifaximin.

COLIDUR FORT contains rifaximin as an active ingredient. COLIDUR FORT is an antibiotic that destroys bacteria that settle in the intestine and cause hepatic encephalopathy. hepatic encephalopathy; In sudden or chronic liver failure, harmful substances that the liver cannot clean are carried to the brain through the blood and cause disorders such as mental tension, aggression, confusion, muscle problems, difficulty in speaking and coma. COLIDUR FORT is used to reduce the recurrence of episodes of significant hepatic encephalopathy in adults with liver disease. It is used in the treatment of chronic gastrointestinal disorders characterized by diarrhea predominantly abdominal pain, swelling and changes in bowel regularity.

COLIDUR FORT can be used alone or in combination with an intestinal softener commonly containing lactulose.

2. Things to consider before using COLIDUR FORT

DO NOT USE COLIDUR FORT in the following conditions

If:

- If you are hypersensitive to rifaximin, antibiotics of similar type to other rifamycins (eg rifampicin or rifabutin) or any of the excipients in the above-mentioned composition of the drug (if you think you may be allergic),
- If you have a fever,
- If you have had 8 or more irregular stools in the last 24 hours,
- If you have ulcers, constipation or obstruction in your intestines,
- Inform your doctor if you have kidney dysfunction,
- If you have diarrhea with bloody stools and fever,
- Rifaximin; Do not use together with a similar type of antibiotic (such as rifampicin or rifabutin).

USE COLIDUR FORT CAREFULLY in the following situations

If:

- If your symptoms worsen during the treatment, stop taking COLIDUR FORT and consult your doctor.
- Your urine may turn red while you are taking COLIDUR FORT. This is normal.

- Treatment with antibiotics containing rifaximin may cause diarrhoea. This can last for months after you stop taking the drug. If diarrhea occurs during or after treatment with COLIDUR FORT; Stop taking COLIDUR FORT and consult your doctor immediately.
- If your liver problem is serious; your doctor will need to monitor you.
- Your doctor will monitor you for changes in your serum sodium and potassium levels.
- Escherichia coli, a bacterium that plays a role in the synthesis of rifaximin vitamin K.

Your doctor will monitor the clotting status of your blood.

- Rifaximin; Be careful when using drugs such as cyclosporine (an immunosuppressant drug), verapamil (cardio-circulatory drug), amiodarone (a heart rhythm-regulating drug) simultaneously.

If these warnings apply to you, even at any time in the past, please consult your doctor.

Taking COLIDUR FORT with food and drink

Taking it with or without food does not change its effect. It should be taken orally with a glass of water.

Pregnancy

Consult your doctor or pharmacist before using this medication.

The harm of COLIDUR FORT to the unborn baby is unknown. Therefore, COLIDUR FORT should not be used while pregnant.

If you realize that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist before using this medication.

It is not known whether rifaximin passes into breast milk. Therefore, do not use COLIDUR FORT during breastfeeding.

Vehicle and machine use

COLIDUR FORT normally does not adversely affect the ability to drive and use machines, but may cause dizziness in some patients. If you feel dizzy, do not drive or use machinery.

Important information about some of the ingredients of COLIDUR FORT

If you are not hypersensitive to the excipients contained in COLIDUR FORT, no adverse effects are expected due to these substances.

Concomitant use with other drugs

If you are using one of the following drugs; Inform your doctor:

- Antibiotics (drugs used to treat infections)
- Warfarin (medicine used to prevent blood clotting)
- Antiepileptics (drugs used to treat epilepsy)
- Antiarrhythmics (medicines used to treat abnormal heartbeat)
- cyclosporine (an immunosuppressant drug)
- Oral contraceptives (birth control drugs)

If you are currently using or have recently used any prescription or non-prescription drugs, please inform your doctor or pharmacist about them.

3. How to use COLIDUR FORT?

Instructions for proper use and dose/frequency of administration:

Always take COLIDUR FORT exactly as your doctor has told you. If you are unsure, check with your doctor or pharmacist.

Recommended dosage:

The recommended dose for COLIDUR FORT is two tablets per day. After 6 months of use, your doctor will evaluate you whether to continue the treatment.

COLIDUR FORT is used three times a day for 14 days in the treatment of chronic gastrointestinal disorders characterized by diarrhea predominantly abdominal pain, swelling and changes in bowel pattern. If your symptoms recur, your doctor may repeat your treatment.

Application route and method:

Take the film-coated tablet out of the blister and swallow it whole with a glass of water.

Different age groups:

Use in children:

Since the efficacy and safety of the drug has not been proven in children and adolescents under 18 years of age, its use is not recommended in children and adolescents under 18 years of age.

Use in the elderly:

There is limited experience with the administration of rifaximin in the elderly.

Special use cases:

It has no special use.

If you have the impression that the effect of COLIDUR FORT is too strong or weak, talk to your doctor or pharmacist.

If you use more COLIDUR FORT than you should:

If you have used more of COLIDUR FORT than you should, talk to a doctor or pharmacist.

If you forget to use COLIDUR FORT

Take the missed dose as soon as you remember and take the other dose at the usual time.

Do not take a double dose to make up for forgotten doses.

Effects that may occur when treatment with COLIDUR FORT is terminated:

If you stop using COLIDUR FORT before your treatment is stopped, your symptoms may worsen.

4. What are the possible side effects?

Like all medicines, there may be side effects in people who are sensitive to the substances contained in COLIDUR FORT. The following gastrointestinal side effects may occur as a result of the use of COLIDUR FORT.

Side effects of drugs are classified as follows:

Very common: occurs in at least 1 in 10 patients.

Common: less than 1 in 10 patients, but more than 1 in 100 patients.

Uncommon: less than 1 in 100 patients, but more than 1 in 1000 patients.

Rare :It can be seen in less than 1 in 1,000 patients, but more than 1 in 10,000 patients.

Very rare: less than 1 in 10,000 patients.

Not known : Cannot be estimated from the available data.

If any of the following occur, stop using COLIDUR FORT and IMMEDIATELY inform your doctor or go to the nearest hospital emergency department:

Common:

- Depression
- Dizziness, headache
- Dyspnea
- Pain in the upper abdominal region, abdominal bloating, diarrhea, nausea, vomiting, ascites
- Itching, rash
- Muscle spasm, arthralgia
- Peripheral edema

Uncommon:

- Clostridium (a kind of bacteria) infection, urinary tract infection, candidiasis (a kind of superficial fungal disease)
- Anemia
- Anorexia, hyperkalemia (high potassium)
- Confusional state, anxiety (anxiety), insomnia, excessive desire to sleep (hypersomnia)
- Balance disorder, memory loss (amnesia), seizure (convulsion), attention disorder, decreased sensitivity in nerves (hypoesthesia), memory impairment
- Sudden hot flashes
- Accumulation of water in the lung membrane (Pleural effusion)
- Abdominal pain, varicose bleeding, dry mouth, stomach discomfort
- Muscle pain (myalgia)
- Painful urination (dysuria), frequent urination (pollakiuria)
- Edema, fever
- Falling

Rare:

- Lung inflammation (pneumonia), cellulitis, upper respiratory tract infection, cold
- Water loss
- High and low blood pressure than normal

- Chronic obstructive pulmonary disease
- Constipation
- Back pain
- Presence of protein in the urine
- weakness (asthenia)
- Confusion, procedural pain

Frequency not known:

- Decrease in the number of platelets (thrombocytopenia)
- Hypersensitivity reactions, edema, hypersensitivity
- Presyncope (feeling faint), syncope (fainting)
- Abnormality in liver function tests
- Inflammatory disease of the skin (dermatitis), skin rash (eczema)
- International normalized rate anomalies

During long-term treatment at high doses or when there is damage to the lining of the gut, a small amount (less than 1%) of the product may be absorbed and cause the urine to turn reddish.

If you experience any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

5. Storage of COLIDUR FORT

Keep COLIDUR FORT out of the sight and reach of children and in its package.

Store at room temperature below 25°C and in its original packaging.

Use in accordance with expiration dates.

Do not use COLIDUR FORT after the expiry date on the package.

Do not use COLIDUR FORT if you notice any defects in the product and/or its packaging.

Do not throw away expired or unused medicines! Give it to the collection system determined by the Ministry of Environment and Urbanization.

License owner:

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Balgat/ANKARA TURKEY

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Çubuk/ANKARA TURKEY

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