PATIENT INFORMATION LEAFLET FOR XIFAXAN

SCHEDULING STATUS

S4

APPROVED
Equity Regulatory
Sign: Jamare Date: 14 July 2020

XIFAXAN 550 mg film-coated tablet

Rifaximin

Sugar free

Read all of this leaflet carefully before you start taking XIFAXAN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- XIFAXAN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What XIFAXAN is and what it is used for

XIFAXAN contains the active substance rifaximin in the gut.

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

XIFAXAN should be used together with medicines containing lactulose (a laxative).

2. What you need to know before you take XIFAXAN

Do not take XIFAXAN:

- if you are hypersensitive (allergic) to:
  - rifaximin
  - similar types of antibiotics (such as rifampicin or rifabutin)
  - any of the other ingredients of XIFAXAN
- if you have a blockage in your intestine

Warnings and precautions

Talk to your doctor or pharmacist before taking XIFAXAN.

While you are taking XIFAXAN your urine may turn a reddish colour. This is not harmful.

Treatment with any antibiotic including XIFAXAN may cause severe diarrhoea. This can happen several months after you have finished taking XIFAXAN. If you have severe diarrhoea during or after using XIFAXAN you should stop taking XIFAXAN and contact your doctor immediately.

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

Children and adolescents

XIFAXAN is not recommended for children and adolescents aged under 18 years. XIFAXAN has not been studied in children and adolescents.

Other medicines and XIFAXAN

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional 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)
- anti-epileptic medicines (for the treatment of epilepsy)
- antidysrhythmic medicines (to treat abnormal heartbeat)
- cyclosporin (immunosuppressor)

- oral contraceptives

Taking XIFAXAN with food and drink

XIFAXAN can be taken with or without food.

Pregnancy and breastfeeding

You should not use XIFAXAN if you are pregnant.

It is not known if XIFAXAN can harm your unborn baby. XIFAXAN is therefore not to be used if you are pregnant.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking XIFAXAN.

You should not breastfeed your baby if you are taking XIFAXAN.

It is not known if rifaximin may be passed to your baby in breast milk. XIFAXAN is therefore not be used if you are breastfeeding.

Driving and using machinery

XIFAXAN may cause dizziness in some patients. If you feel dizzy you should not drive or operate machinery. It is not always possible to predict to what extent XIFAXAN may interfere with your daily activities. You should ensure that you do not engage in driving or using machinery until you are aware of the measure to which XIFAXAN affects you.

3. HOW TO TAKE XIFAXAN

Do not share medicines prescribed for you with any other person.

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

The recommended dose of XIFAXAN is one tablet twice daily taken with a glass of water.

XIFAXAN can be taken with or without food.

Your doctor will assess the need for you to continue treatment after 6 months.

If you take more XIFAXAN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre.

If you forget to take a dose of XIFAXAN

Take the next dose at its normal time.

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

If you stop taking XIFAXAN

Do not stop taking XIFAXAN 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

XIFAXAN can have side effects.

Not all side effects reported for XIFAXAN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking XIFAXAN, please consult your healthcare provider for advice.

Stop taking XIFAXAN and tell your doctor immediately if you have any of the following side effects:

- 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.
- 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:

- 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
- 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 and 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 fluid retention in the body)
- falls
- 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
- 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)

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of XIFAXAN.

5. How to store XIFAXAN

Store at or below 25 °C.

Keep the tablets in the blister strip and the strips in the outer carton until required for use.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the blister and carton

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What XIFAXAN 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.

Film-coat (Opadry OY-S-34907): hypromellose, titanium dioxide (E171), disodium edetate, propylene glycol, red iron oxide (E172).

Sugar free.

What XIFAXAN looks like and contents of the pack

Pink, oval biconvex film-coated tablets embossed with RX on one side.

Transparent PVC/PE/PVDC/Aluminium blister strips in cardboard boxes.

Pack size: 56 tablets

Holder of Certificate of Registration

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