

XIFAXAN 550 mg Tablets

Rifaximin

Consumer Medicine Information

What is in this Leaflet

This leaflet answers some common questions about XIFAXAN tablets.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What XIFAXAN is used for:

XIFAXAN is an antibiotic that passes through the gastrointestinal tract and very little is absorbed. XIFAXAN is used to help prevent a condition called **hepatic encephalopathy (HE)**. HE is a disease of the brain that occurs when the liver is not working properly. Symptoms are caused by too much ammonia in the blood. XIFAXAN works by killing bacteria in the gut that produce ammonia. This means less ammonia is produced and less gets into the blood.

XIFAXAN is intended to be used for preventing HE only in those patients where HE is likely to occur again, and where it cannot be managed with other treatments.

There is no experience using XIFAXAN to prevent the

recurrence of HE in children or adolescents.

Ask your doctor or pharmacist if you have any questions about why XIFAXAN has been prescribed for you.

Your doctor may have recommended XIFAXAN tablets for another reason.

Before you take XIFAXAN

When you must not take it

Do not take XIFAXAN tablets if:

- You have an allergy to rifaximin or any of the rifamycin antibiotics (rifampicin, rifabutin) or to any other ingredient contained in this medicine, listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itchiness or hives on the skin.
- You have bowel obstruction (a blocked bowel)

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor can discuss with you the risks and benefits involved.

Tell you doctor if you are breastfeeding.

It is not know if your baby can absorb rifaximin from breast milk if you are breastfeeding.

If you have not told your doctor about any of the above, tell him/her before you start taking XIFAXAN tablets.

Taking other medicines

Tell you doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Your doctor and pharmacist have more information on which medicines to be careful with or avoid while taking this medicine.

How to take XIFAXAN tablets

How much to take

The recommended dosage of XIFAXAN tablets is one tablet twice daily.

How to take it

Swallow the tablet whole with a glass of water. You can take

XIFAXAN tablets with or without food.

If you forget to take it

If your next dose is due within 12 hours, skip the dose you missed and take the next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to the Accident and Emergency department at the nearest hospital, if you think that you or anyone else may have taken too many XIFAXAN tablets. Do this even if there are no signs of discomfort or poisoning.

While you are using XIFAXAN tablets

Things you must do

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you develop watery and bloody diarrhoea (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of XIFAXAN you should see your doctor as soon as possible. If diarrhoea occurs, gets worse or does not improve during therapy, you should also contact your doctor.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any

medicine to treat diarrhea without first checking with your doctor.

Things you must not do

Do not take XIFAXAN tablets to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using XIFAXAN.

All medicines can have unwanted effects. Sometimes they are serious, most of the time they are not. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions that you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Swelling of the extremities
- Nausea
- Dizziness
- Fatigue
- Itching
- Muscle pain

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- Diarrhoea. XIFAXAN, like nearly all antibiotics, can alter the mix of bacteria in the intestine. This can lead to an overgrowth of a bacteria called

Clostridium difficile (*C. difficile*). If you take XIFAXAN, there is a small risk that you could experience diarrhoea caused by *C. difficile*. If you develop severe diarrhoea, even after you have stopped XIFAXAN, contact your doctor immediately.

As with other medicines there is a small risk of serious allergic reaction. Consult your doctor immediately or go to the Accident & Emergency department of your nearest hospital if you notice any of the following:

- swelling of the face, lips or tongue which may make swallowing or breathing difficult
- asthma, wheezing, shortness of breath
- sudden or severe itching, skin rash, hives

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using XIFAXAN tablets

Storage

Keep your tablets in the blister packaging until it is time to take them

If you take the tablets out of the packaging they will not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store XIFAXAN tablets or any other medicines in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

XIFAXAN 550 mg tablets are oval, biconvex, pink, film-coated tablets.

Ingredients

XIFAXAN tablets contains 550 mg of rifaximin as the active ingredient.

The tablets also contains:

- Cellulose – microcrystalline
- Glyceryl diisostearate
- Sodium starch glycolate Type A
- Silica-colloidal anhydrous
- Talc – purified

The film coating contains

- Hypromellose
- Titanium dioxide
- Disodium edetate
- Propylene glycol
- Iron oxide red

Supplier

XIFAXAN tablets are supplied in Australia by:

Norgine Pty Ltd
3/14 Rodborough Road
Frenchs Forest NSW 2086
AUSTRALIA
1800 766 936

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