

XIFAXAN 200 mg Tablets

Rifaximin

Consumer Medicine Information

What is in this Leaflet

This leaflet answers some common questions about XIFAXAN 200 mg 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 200 mg is used for:

XIFAXAN is an antibiotic that passes through the gastrointestinal tract and very little is absorbed. XIFAXAN 200 mg is used to treat travellers' diarrhoea that is caused by bacteria that do not invade the gut wall, in people aged 12 years and older. XIFAXAN is not effective for diarrhoea caused by bacteria that invade the gut wall. There is no experience using XIFAXAN to treat travellers' diarrhoea in children under 12 years of age. XIFAXAN may be prescribed for you before you travel overseas, so you have it with you if you need to treat an episode of diarrhoea.

Before you travel overseas, ask your doctor or pharmacist if you have any questions about why XIFAXAN has been prescribed for you, or how to use it.

Your doctor may have recommended XIFAXAN tablets for another reason.

Before you take XIFAXAN 200 mg

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)
- You also have a fever, or blood in your stools. These are signs that the diarrhoea may be caused by an invasive bacteria that will not be effectively treated by XIFAXAN.

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, see medical advice.

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 known 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.

There is a possibility that XIFAXAN can interact with other medicines, including ciclosporin, oral contraceptives and warfarin.

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

How to take XIFAXAN 200 mg tablets

How much to take

The recommended dosage of XIFAXAN tablets is one 200 mg tablet three times a day for three days (a total of 9 doses).

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 it is nearly time for your next dose, 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)

If in Australia, 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. If overseas, seek medical advice. 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 experience fever, if your diarrhoea becomes worse, you have blood in your stools, or if symptoms have not resolved after 3 days of treatment, then contact a doctor for assessment. Do not take a second course of XIFAXAN.

Things you must not do

Do not take XIFAXAN tablets to treat any other conditions 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 a 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 a doctor or pharmacist to answer any questions that you may have.

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

- dizziness, headache
- wind, abdominal bloating, abdominal pain, constipation, diarrhoea

- involuntary, painful, or ineffective straining on the toilet
- nausea, vomiting
- fever

The above list includes the more common side effects of your medicine reported in adults being treated for traveller's diarrhoea. They are usually mild and short-lived.

Less common side effects include:

- Thrush, cold sore, swollen throat, inflammation or infection of the nose or throat
- Loss of appetite, dehydration
- Depressed mood, sleeplessness, nervousness
- Earache
- Cough, dry or sore throat, runny nose, shortness of breath, blocked nose
- Muscle cramps, muscle pain, back or neck pain
- Chills, cold sweats, perspiration, flu-like illness
- Rash, blotchy skin, hot flushes.

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 after you have stopped XIFAXAN, contact your doctor immediately.

As with other medicines there is a small risk of serious allergic reactions. 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 200 mg tablets are pink, round, biconvex, film-coated tablets.

Ingredients

XIFAXAN tablets contains 200 mg of rifaximin as the active ingredient.

The tablets also contain:

- Microcrystalline cellulose
- Glyceryl diisostearate
- Sodium starch glycolate Type A
- Colloidal anhydrous silica
- Purified talc

The film coating contains

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

Supplier

XIFAXAN tablets are supplied in Australia by:

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