

Rifaximin for pouchitis

Information for the public

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About this information

This information explains the evidence summary about the off-label use of rifaximin for treating pouchitis. The evidence summary is an overview of the available information about this medicine. It aims to help prescribers and patients when they are considering whether or not to use an unlicensed or off-label treatment. The summary does not contain recommendations from NICE on whether the medicine should be used.

Licensing medicines

In the UK, medicines need to have a licence before they can be marketed. To get a licence, the manufacturer of the medicine has to provide evidence that shows that the medicine works well enough and is safe enough to be used for a specific condition and for a specific group of patients, and that they can manufacture the medicine to the required quality. Medicines can be prescribed without a licence (an 'unlicensed medicine') if there is no suitable licensed alternative and it is likely to benefit the patient.

A medicine can also be prescribed 'off-label'. This means the prescriber wants to use it in a different way than is set out in the terms of its licence. This could mean using the medicine for a different condition or a different group of patients, or it could mean a change in the dose or that the medicine is taken in a different way. There is more information about licensing medicines on [NHS Choices](#).

What is pouchitis?

Some people need to have their large bowel (colon) removed by surgery. This is usually because they have a condition called ulcerative colitis that causes inflammation and ulcers in the large bowel, or because they have another disease in the large bowel, such as cancer. After removing the large bowel, it may be possible for the surgeon to make a 'pouch' out of the last part of the small bowel to connect it to the anus (or back passage) so that people can still pass stools in the normal way. This pouch acts as a 'reservoir' to collect stools before the person is ready to pass them in the normal way through a bowel movement.

When someone has pouchitis, it means that the pouch has become inflamed. A person with pouchitis may have symptoms such as needing to open their bowels even more frequently, feeling they need to get to the toilet urgently, having tummy cramps, and noticing that the stool is even more watery than usual. Some people may also notice blood in the stool, or feel generally unwell and have a high temperature.

People who have pouchitis are usually given a 2-week course of antibiotics (usually either ciprofloxacin or metronidazole). Most people will get better after taking 1 of these antibiotics; however, about 1 in 10 people will not. If the person has not got better after taking a 2-week course of antibiotics and they have been unwell for longer than 4 weeks, then the condition is called 'chronic' pouchitis. This can be a bit harder to treat, and other treatment options may be considered.

Pouchitis also develops again in more than half of people who initially recover. Some people need to have repeated courses of antibiotics, and some people, even when they have recovered, may need to stay on long-term treatment to try and prevent pouchitis from coming back.

About rifaximin

Rifaximin is an antibiotic that is taken by mouth. It is licensed to treat traveller's diarrhoea, and to treat a condition called hepatic encephalopathy, where people with liver failure develop problems with their brain function (such as confusion, memory problems and altered behaviour). Rifaximin is not licensed to treat pouchitis, and so this would be an off-label use of rifaximin.

Rifaximin is 1 of the treatment options that may be considered for people who have pouchitis that has not got better with other antibiotics. It may be given by itself, or it may be given with an antibiotic called ciprofloxacin.

Summary of possible benefits and harms

How well does rifaximin work?

Three small studies have looked at how well rifaximin works when it is used to treat pouchitis, and 1 small study has looked at using rifaximin to prevent pouchitis coming back after it has been treated.

One study that looked at using rifaximin to treat pouchitis included 18 people; almost all of them had tried antibiotics to treat their pouchitis but they had not got better. About half of the people in the study were given rifaximin for 4 weeks, and the other people were given a 'dummy' tablet (which didn't contain any antibiotics) instead. Two of the people given rifaximin got better, but the other 6 people who took it didn't get better. None of the people given the 'dummy' tablet got better. Because this study included only 18 people, it cannot reliably tell us whether rifaximin does or does not work for treating pouchitis, because the results may just have been due to chance.

The 2 other studies that looked at using rifaximin to treat pouchitis did not compare rifaximin with any other tablet; they just report what happened when some people were given rifaximin for pouchitis. The studies were very similar and included a total of 26 people with chronic pouchitis. None of the people had got better after taking antibiotics that are usually used first for treating pouchitis. The people in these 2 studies were given rifaximin along with another antibiotic (ciprofloxacin) for 2 weeks. Most people in both of these studies got better after taking both antibiotics together (16 of 18 people in 1 study, and 5 of 8 people in the other). However, because these 2 studies didn't include many people, and they did not compare rifaximin with any other treatments, they can't reliably tell us how good rifaximin is for treating pouchitis.

One other study included 51 people who had got better after taking antibiotics for their pouchitis, but once they stopped taking antibiotics, the pouchitis would come back. Therefore this study wanted to see whether taking rifaximin for a long period of time (from a few months up to 2 years) would stop these people from getting pouchitis again. After 3 months, 33 out of 51 people taking rifaximin were still well. Again, because this study didn't include many people, and it did not compare rifaximin with any other treatments, it can't reliably tell us how good rifaximin is at stopping pouchitis coming back after it has been treated.

What are the possible harms or side effects?

In these 4 small studies in people with pouchitis, rifaximin caused very few side effects. However, in other studies where rifaximin has been used to treat other conditions, common side effects noticed

by more than 1 out of 100 people who took rifaximin have included dizziness and headaches, and tummy symptoms like pain, swelling, sickness, diarrhoea or constipation. As with several other antibiotics, there is the rare possibility that rifaximin could cause severe diarrhoea.

Please note that the results of the research studies only indicate the benefits and harms for the population in the studies. It is not possible to predict what the benefits and harms will be for an individual patient being treated with rifaximin.

Prescribing rifaximin

If a prescriber wants to use an unlicensed or off-label medicine, they must follow their professional guide, for example for doctors the General Medical Council's [good practice guidelines](#). These include giving information about the treatment and discussing the possible benefits and harms so that the patient has enough information to decide whether or not to have the treatment. This is called giving informed consent.

A [full version of the summary aimed at healthcare professionals](#) is available on the NICE website. The summary for healthcare professionals does not contain recommendations from NICE on whether the medicine should be used.

Questions to ask

- Why am I being offered an off-label medicine?
- What does the treatment involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits?
- Could having the treatment make me feel worse?
- Are there alternative treatments?
- What are the risks of the treatment?
- Are the risks minor or serious? How likely are they to happen?
- What may happen if I don't have the treatment?

More information

The evidence summary and this information for the public were produced for NICE by Bazian Ltd.

NICE has published [information](#) about how evidence summaries for unlicensed and off-label medicines are developed.

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