

Colesevelam for problems with absorbing bile acid (bile acid malabsorption)

Information for the public

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About this information

This information explains the evidence summary about the off-label use of colesevelam for problems with absorbing bile acid (bile acid malabsorption). 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 bile acid malabsorption?

Bile is essential for us to digest fats that we eat. When we eat, bile is released from the gall bladder into the small intestine where fats are broken down and absorbed into the body. Normally most of the bile is then reabsorbed from the small intestine and recycled, with only a small amount reaching the large intestine (colon), where it is removed in the stools.

People with problems reabsorbing bile acid (bile acid malabsorption) have more bile than normal in the colon. This extra bile makes the colon release more water and speeds up the time it takes for waste to pass through the colon. This results in chronic watery diarrhoea.

Bile acid malabsorption is found in a number of conditions. For example, it can be caused by diseases of the small intestine, such as Crohn's disease, and it is seen in people who have had an operation to remove or bypass their small intestine. However, sometimes it occurs when the small bowel appears normal; the reason for bile acid malabsorption in this situation is not known.

Although not life threatening, bile acid malabsorption can have a big effect on lifestyle and quality of life because the increased need to pass motions may limit the person's ability to travel and leave the house.

About colesevelam

Colesevelam is licensed for treating primary hypercholesterolaemia in adults. Primary hypercholesterolaemia is a condition in which levels of cholesterol in the blood are higher than normal.

Colesevelam works by binding to bile acids in the intestine and stopping them from being

reabsorbed. Bile acids are made from cholesterol. When colesevelam binds to bile acids, the body uses cholesterol to make more bile acid, so reducing cholesterol levels in the blood.

Colesevelam is sometimes used for bile acid malabsorption because when it binds to bile acids it reduces their effects on the colon, including diarrhoea. Colesevelam does not have a UK licence for treating bile acid malabsorption.

There are 2 other drugs that work in a similar way and are licensed for treating hypercholesterolaemia. These are called colestyramine and colestipol. They are also sometimes used to treat bile acid malabsorption. Colestipol is not licensed for this; colestyramine is licensed for treating diarrhoea in some conditions that may cause bile acid malabsorption. These drugs are powders which have to be mixed with water or another liquid before they are taken, and some people find that they have an unpleasant taste. Colestyramine and colestipol have some side effects including constipation (when stools are not passed regularly), nausea (feeling sick), stomach rumbling, flatulence (wind), bloating and abdominal pain.

Summary of possible benefits and harms

How well does colesevelam work?

One study compared colesevelam with a 'dummy' tablet (known as placebo) in 24 women with irritable bowel syndrome and diarrhoea as a main symptom. Four of the women were thought to have bile acid malabsorption. In the 24 women, colesevelam did not reduce the time it took for a meal to pass through the digestive system compared with the dummy tablet. Reducing this time could reduce diarrhoea. Colesevelam did make it easier to pass stools, but did not reduce the number of stools passed each day or the stool consistency (if stools were watery or hard) compared with the dummy tablet.

Another study looked at how well colesevelam worked in 45 people who had received treatment for cancer. These people had symptoms of bile acid malabsorption for at least 3 months. Out of the 45 people, 30 had previously tried colestyramine, but it had not helped. Colesevelam reduced how often and how urgently people had to empty their bowels, bowel incontinence (involuntary passage of stools) and tummy pain.

Another study looked at how well colesevelam worked for treating bile malabsorption, but

included only 5 people. All 5 had previously tried colestyramine but were not able to take it. In these 5 people, colesevelam reduced diarrhoea.

What are the possible harms or side effects?

The most common side effects of colesevelam (seen in at least 1 in every 10 people) are flatulence (wind) and constipation. Other side effects include headache, feeling sick and vomiting, diarrhoea, indigestion, abnormal stools, tummy pain and bloating (seen in between 1 in every 100 people and 1 in every 10 people), difficulty swallowing, muscle pain (seen in between 1 in every 1000 people and 1 in every 100 people) and pancreatitis (inflammation of the pancreas, seen in fewer than 1 in every 10,000 people).

Colesevelam may reduce how well some other drugs are absorbed. Therefore, colesevelam should be taken at least 4 hours before or at least 4 hours after other medication.

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 colesevelam.

Prescribing colesevelam

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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