



# Erythromycin for gastroparesis (delayed stomach emptying)

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#### About this information

This information explains the evidence summary about the off-label use of erythromycin for gastroparesis (delayed stomach emptying). 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 gastroparesis?

Gastroparesis is a condition where the stomach does not empty itself of food as quickly as it should. This can lead to symptoms like feeling full very quickly when eating, feeling bloated, having pain or discomfort in the upper part of the tummy, and feeling or being sick.

It is thought that gastroparesis happens when there is a problem with the nerves or muscles that control emptying of the stomach. If the nerves are damaged, then the stomach doesn't work properly which means that food isn't moved out of the stomach as quickly as normal. Most of the time, it isn't known what has caused the nerve damage (this is sometimes called 'idiopathic' gastroparesis). However, gastroparesis is sometimes seen in people with diabetes, where the nerves to the stomach are damaged by high levels of glucose in the blood. Gastroparesis can also happen in people who have had surgery on their stomach.

# **About erythromycin**

Erythromycin is an antibiotic that is licensed to treat various infections of the chest, digestive system, ear, eye, mouth and skin. Erythromycin is usually taken by mouth as tablets, capsules or as a liquid every 6 to 12 hours.

The most important thing to keep people with gastroparesis healthy is making sure that they receive the food and liquid they need. Erythromycin is 1 of a few medicines that may be used to try and increase the activity of the stomach to help it to empty more quickly. There are 2 other drugs that may sometimes be used to treat gastroparesis. These are called metoclopramide and domperidone.

## Summary of possible benefits and harms

### How well does erythromycin work?

Only 4 small studies (which included a total of 48 people) were found that looked at how well erythromycin works for improving symptoms in people with gastroparesis. The people in these studies took erythromycin tablets, capsules or liquid in varying amounts, ranging from 125 mg taken 3 times a day, to 500 mg taken 4 times a day. The length of time that people took erythromycin for also varied, ranging from 2 to 4 weeks.

One study found that erythromycin did not work any better than a dummy tablet for improving symptoms of gastroparesis. A dummy tablet is a tablet that doesn't contain any active ingredient, and is also called a 'placebo'. Another study found that erythromycin worked better than metoclopramide (one of the other possible treatments that can be used for gastroparesis) for improving symptoms. Two studies didn't compare erythromycin with any other treatment, but they found that taking erythromycin did not help make people's symptoms better.

Overall, the 4 studies were of poor quality and do not provide reliable evidence on how well erythromycin works at improving the symptoms of gastroparesis.

#### What are the possible harms or side effects?

None of the 4 studies looked at how safe it is to use erythromycin, or the possible harms or side effects that using it may cause.

However, it is known that erythromycin can cause unpleasant side effects. Most commonly, it can cause stomach pains, feeling sick (nausea), being sick (vomiting) and diarrhoea. It can also cause more severe side effects, although these are rare, including loss of hearing, allergic reactions, liver problems, heart rhythm problems, and swelling (or inflammation) of the bowel. Erythromycin can also react with a wide variety of other medicines, and there are a number of people who would not be able to take erythromycin, including those taking certain tablets to lower their cholesterol. The treating doctor would need to review the person's current medicines before prescribing erythromycin to ensure that it would be safe for the person to take it.

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

# Prescribing erythromycin

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 <u>full version of the summary aimed at healthcare professionals</u> 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 <u>information</u> about how evidence summaries for unlicensed and offlabel medicines are developed.

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