Azithromycin for long-term treatment of damaged airways (bronchiectasis) in people without cystic fibrosis

Information for the public
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About this information

This information explains the evidence summary about the off-label use of azithromycin for long-term treatment of damaged airways (bronchiectasis) in people without cystic fibrosis. 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.

Use of azithromycin for the long-term treatment of cystic fibrosis is covered in another evidence summary.

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 bronchiectasis?

Bronchiectasis is a condition in which the passages that bring air into the lungs (airways) are inflamed, damaged and widened. The airways produce a sticky substance called mucus that traps any dust, dirt and bacteria. In people with bronchiectasis, the inflamed, damaged and widened airways cannot clear mucus as well as a normal airway can. This means that the mucus builds up, causing people to cough up phlegm (sputum). Bacteria can build up in the mucus causing chest infections. Other common symptoms of bronchiectasis include wheezing, chest pain, feeling short of breath and feeling tired. People with bronchiectasis may have to be admitted to hospital because of repeated chest infections.

Bronchiectasis can have several causes, including past pneumonia, lung problems present from birth, and problems with the body’s defence system that increase the chance of chest infections. However, often the cause is not known.

Some guidelines that doctors use for treating bronchiectasis advise that long-term antibiotics should be considered for people who have 3 or more chest infections a year, or for people who have fewer chest infections than this, but the chest infections are causing a lot of problems.

About azithromycin

Azithromycin is an antibiotic, however it can also reduce inflammation. As an antibiotic it is usually only used for a few days, but it is sometimes used for longer periods to reduce inflammation.

In the UK, azithromycin is licensed for treating certain infections (bronchitis, pneumonia, sinusitis, pharyngitis and tonsillitis, otitis media, skin and soft tissue infections, and genital infections). Azithromycin is also used for long-term treatment of bronchiectasis in people without cystic fibrosis, but this use is off-label.
Summary of possible benefits and harms

How well does azithromycin work?

There are only a few studies that have looked at how well long-term azithromycin works for treating bronchiectasis in people who don't have cystic fibrosis.

One study compared azithromycin (250 mg taken once a day for 12 months) with dummy tablets (these don't have any medicine or antibiotic in them and are also known as placebo) in 89 adults with bronchiectasis but without cystic fibrosis. It found that the number of chest infections needing a short course of another antibiotic was lower in people who took azithromycin than in people who took the dummy tablets. People who were taking azithromycin also found that their symptoms, such as cough and breathlessness, quality of life and lung function improved compared with people who took dummy tablets.

A similar study compared a different dose of azithromycin (500 mg taken on Mondays, Wednesdays and Fridays for 6 months) with dummy tablets in 141 adults with bronchiectasis but without cystic fibrosis. This study also found that the number of chest infections needing a short course of antibiotics was lower in people who took azithromycin than in people who took the dummy tablets. This difference continued for 6 months after the treatment finished. However, there was no change in quality of life, lung function or the ability to exercise in people taking azithromycin compared with those taking the dummy tablets.

Both studies included only adults and it isn't clear how well long-term azithromycin works for treating bronchiectasis in children who don't have cystic fibrosis. The studies also used different doses of azithromycin and lasted for different lengths of time so it isn't clear what the best dose is to use or how long treatment should last.

What are the possible harms or side effects?

There is little information about how safe it is to take azithromycin over a long period (6 to 12 months). However, in the 2 studies, side effects were usually mild or moderate and very few people stopped taking azithromycin because of them.

Diarrhoea, stomach pain, nausea (feeling sick) and wind (flatulence) are very common with azithromycin (occurring in at least 1 in 10 people).
Sometimes people have hearing loss after taking azithromycin for a long time, although hearing does return after stopping treatment. Occasionally, azithromycin can cause abnormal heart beats in some people.

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 azithromycin.

Prescribing azithromycin

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

NICE has published information about how evidence summaries for unlicensed and off-label medicines are developed.

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