

Ramipril for peripheral arterial disease

Information for the public

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About this information

This information explains the evidence summary about the off-label use of ramipril for managing symptoms of peripheral arterial disease, a condition in which the blood supply to leg muscles is reduced. 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 it 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 peripheral arterial disease?

In people with peripheral arterial disease (also called peripheral vascular disease), the blood vessels (arteries) that carry blood to the legs become hardened and narrowed or blocked by a build-up of fatty deposits. The most common symptom of peripheral arterial disease is a cramp-like pain in the legs while walking or exercising, which stops after resting. This is called intermittent claudication.

People who have peripheral arterial disease are at risk of other problems with their heart or blood vessels (called cardiovascular disease). These include angina or a heart attack (if the flow of blood to the heart is reduced) or a stroke (if the flow of blood to the brain is reduced). This is because when the blood vessels in the legs and feet are narrowed or blocked by fatty deposits, it is likely that other blood vessels in the body are affected too.

Treatments for peripheral arterial disease aim to relieve pain in the legs during exercise (intermittent claudication) and reduce the risk of angina, heart attack and stroke. They include lifestyle changes (such as stopping smoking, losing weight and taking more exercise) and medicines to control cholesterol levels, blood pressure and diabetes. If these don't improve the symptoms, a medicine called naftidrofuryl oxalate is sometimes used.

More information is available in the NICE guideline on [peripheral arterial disease](#).

About ramipril

Ramipril is licensed in the UK to treat high blood pressure (hypertension) and heart failure, and to reduce the risk of heart attacks, strokes and kidney problems. It is taken by mouth as a tablet or liquid.

Ramipril is sometimes used to treat leg pain during exercise (intermittent claudication) in people with peripheral arterial disease, but it isn't licensed in the UK for this. Use in this way is therefore off-label.

Summary of possible benefits and harms

How well does ramipril work?

Two small studies have looked at how well ramipril improves leg pain during exercise (intermittent claudication) in people with peripheral arterial disease. Each study lasted 24 weeks.

A study of 40 people found that those who took ramipril could walk for about 7 and a half minutes longer than those who took placebo (a dummy tablet). People taking ramipril were also able to walk without pain for about 4 minutes more than people taking placebo. A second study of 33 people looked at walking distance instead of walking time. It found that people who took ramipril could walk about 131 metres further, and were pain-free for about 122 metres more than people who took placebo.

Most people in the studies were white. It is known that ramipril works less well in people of African or Caribbean family origin, so the study results may not apply to these groups. Both of the studies compared ramipril with placebo so it is not known how ramipril compares with other treatments such as naftidrofuryl oxalate. The studies lasted for only 24 weeks and it is not known how well ramipril will work over a longer period.

What are the possible harms or side effects?

The most common side effects of ramipril (seen in between 1 in 10 and 1 in 100 people) include headache, dizziness, tickly cough, inflammation of the sinuses, shortness of breath, upset stomach or gut, rash, cramps or muscle pains, low blood pressure or fainting, chest pain and tiredness.

No side effects were reported in 1 of the studies of ramipril for peripheral arterial disease. The side effect reported most often in the other study was cough, which caused a few people to stop their treatment.

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 ramipril.

Prescribing ramipril

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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