

Sildenafil for ulcers on fingers and toes

Information for the public
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About this information

This information explains the evidence summary about the off-label use of sildenafil for ulcers that are on the fingers or toes (digital ulcers). 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 are digital ulcers?

Ulcers on the fingers or toes are known as digital ulcers. These can happen in people with a severe form of Raynaud's phenomenon (also just called Raynaud's). Raynaud's affects the blood supply to the fingers and toes. These change colour and may become painful in cold weather, with a change in temperature, or with emotional stress. The severe form of Raynaud's is usually caused by a condition called systemic sclerosis, in which a person's immune system damages some of the cells in their body. The skin tissue in the fingers or toes becomes damaged and ulcers develop. These are painful and often cause problems with daily tasks, such as eating or dressing.

People with Raynaud's can minimise attacks by avoiding the cold, keeping their hands and feet warm with gloves and socks, and by stopping smoking (smoking can also affect blood supply). In some cases, medicines known as calcium channel blockers (for example, nifedipine) are used. These work by relaxing the blood vessels in the fingers and toes, increasing their blood supply. Only 1 medicine, called bosentan (taken as a tablet), is licensed in the UK for treating digital ulcers. This can be offered by specialist doctors to people with systemic sclerosis who already have digital ulcers, to stop new ulcers developing. Bosentan does not help to heal ulcers that have already developed. Other medicines that are used to treat digital ulcers are iloprost (given by infusion in hospital), or 'phosphodiesterase type 5 (PDE5) inhibitors' such as sildenafil (taken as a tablet).

About sildenafil

Sildenafil is a type of medicine called a 'PDE5 inhibitor', which also works by widening blood vessels (but in a different way to calcium channel blockers). It is licensed in the UK for treating a rare condition called pulmonary hypertension. When someone has pulmonary hypertension their blood pressure is too high in the blood vessels in their lungs. By widening the blood vessels in the lungs, sildenafil reduces the pressure in these vessels. Sildenafil is also licensed in the UK for treating erectile dysfunction; it improves blood flow into the penis and helps with erections.

Sildenafil can be used to try and stop new digital ulcers developing and to help existing ulcers heal. It is not licensed specifically for this, and so its use in this way is called 'off-label'. People with ulcers who are prescribed sildenafil by their doctor, usually take it 3 times daily, for a number of weeks but sometimes longer, depending on how well sildenafil works for them and how they feel while taking it.

Summary of possible benefits and harms

How well does sildenafil work?

Two small studies looked at how well sildenafil works compared with dummy treatment for people with Raynaud's. These studies were too small (77 people in total) and carried out for too short a time (4 weeks) to show whether there was a difference between sildenafil and a dummy treatment in healing ulcers. However, when the results of these 2 small studies were looked at with the results of a similar study with another PDE5 inhibitor, called tadalafil, they suggested that this type of drug may be helpful in healing and improving ulcers.

One other small study in 19 people compared the number of digital ulcers people had before and after treatment with sildenafil. This study found that in the 16 people who completed the study, sildenafil reduced the number of ulcers at the end of 6 months of treatment by an average of 2 ulcers per person.

None of the studies compared sildenafil with other medicines used to treat digital ulcers.

What are the possible harms or side effects?

In the small studies that looked at how well sildenafil works for treating digital ulcers, the most common side effects were headache, indigestion, flushing of the face, palpitations and joint and muscle pain. These are very common side effects with sildenafil and can affect more than 1 in 10 people taking this medicine.

People with certain health problems should not take sildenafil for digital ulcers and their doctor will be able to provide more information about this. For example, people should not take sildenafil if they have a severe heart or liver problem, very low blood pressure, or if they have recently had a stroke or heart attack. People with certain rare inherited eye

diseases (such as retinitis pigmentosa), or loss of vision due to non-arteritic anterior ischaemic optic neuropathy should not take sildenafil. People should not take sildenafil if they are allergic to it or if they are also taking certain medicines, for example, medicines called nitrates (for chest pain) or nitric oxide donors such as amyl nitrite ("poppers"), medicines to treat fungal infections such as ketoconazole or itraconazole or medicines containing ritonavir (for HIV).

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

Prescribing sildenafil

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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