

Infliximab for sarcoidosis in organs except the lungs

Information for the public

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About this information

This information explains the evidence summary about the off-label use of infliximab for sarcoidosis in organs in the body other than the lungs (extrapulmonary sarcoidosis). Sarcoidosis in the lungs (pulmonary sarcoidosis) is explained in a [separate publication](#). 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 sarcoidosis?

Sarcoidosis is a rare condition that causes small patches of red and swollen tissue, called granulomas, to develop in the organs of the body. Sarcoidosis affects the lungs in about 9 out of 10 people with the condition (pulmonary sarcoidosis). Other organs such as the skin, eyes, brain, nervous system, liver and heart may also be affected (extrapulmonary sarcoidosis).

It's thought that sarcoidosis is caused by the body's immune system starting to attack its own tissues and organs. This leads to inflammation with patches of swelling and redness (granulomas).

For many people with sarcoidosis, symptoms are not severe and improve in a few months or years without treatment. However, in a few people, symptoms gradually get worse over time and become severe. This is known as chronic sarcoidosis.

If treatment is needed, prednisolone (steroid) tablets are usually used to reduce inflammation. Immunosuppressants are sometimes used if steroids don't work well enough or there are concerns about their side effects. Immunosuppressants may help to improve symptoms because they reduce the activity of the body's immune system.

There is more information on sarcoidosis on [NHS Choices](#).

About infliximab

Infliximab is a type of immunosuppressant, which is given by injection. It stops inflammation by acting on a substance in the body called tumour necrosis factor (TNF) alpha.

Infliximab is licensed in the UK for treating severe flare-ups of the following diseases:

- rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis, in which the joints are inflamed
- Crohn's disease and ulcerative colitis, in which the digestive system is inflamed
- psoriasis, in which the skin is inflamed.

Infliximab is sometimes used to treat sarcoidosis 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 infliximab work?

Ten studies looked at how well infliximab worked for treating severe sarcoidosis, which wasn't improving with the usual treatments, or wasn't improving because people couldn't have the usual treatments. There were 155 instances of sarcoidosis in an organ other than the lung, with 52 in the brain or nervous system and 38 in the skin.

Of these 155 instances of sarcoidosis, after infliximab treatment:

- 51 got better (33% or 33 in 100)
- 71 improved (46% or 46 in 100)
- 10 got better or improved (6% or 6 in 100)
- 22 didn't change (14% or 14 in 100)
- 1 got worse (1% or 1 in 100).

However, we don't know what would have happened if these people hadn't had infliximab. All of the studies were small and of low quality, so better quality evidence is needed to confirm this.

Specialists recommend that immunosuppressants such as infliximab should be used only when sarcoidosis is getting worse, and:

- usual treatments aren't working **or**
- usual treatments can't be used because of the person's other health conditions **or**
- the person has had serious side effects with the usual treatments.

What are the possible harms or side effects?

The most common side effects of infliximab (occurring in at least 1 in 10 people) include aches and pains, infections of the upper respiratory tract (such as sinusitis), viral infections (such as flu and herpes), headaches, stomach pains and feeling sick. People often have a reaction when infliximab is administered into their veins.

Most side effects of infliximab are mild or moderate. However, some people have serious side effects, which may need treating. In most of the studies, a few people had to stop taking infliximab because of serious side effects.

People should be tested for hepatitis B virus and tuberculosis (TB) before starting infliximab. They should also be monitored closely for infections before, during and 6 months after finishing treatment.

Please note that the results of the research study 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 infliximab.

Prescribing infliximab

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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