

# Mycophenolate for systemic lupus erythematosus

Information for the public

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## About this information

This information explains the evidence summary about the off-label use of mycophenolate for treating systemic lupus erythematosus (often called SLE). 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 systemic lupus erythematosus?

Systemic lupus erythematosus (or SLE for short) is an autoimmune condition, which means it is caused by problems with the immune system (the body's natural defence against illness and infection). In people with SLE, the immune system starts to attack healthy cells, tissue and organs. The reasons for this aren't clearly understood.

Common symptoms of SLE include tiredness, joint pain and skin rashes. Some people may have only mild symptoms whereas others may be more severely affected. Many people will have long periods of time with few or no symptoms (called 'remission') before experiencing a sudden flare-up when their symptoms are particularly severe (called 'a relapse').

SLE can sometimes cause serious complications, such as kidney failure or heart disease, and some treatments for SLE can make a person vulnerable to serious infections. Lupus nephritis is a complication of SLE in which the kidneys become inflamed, and can't work normally.

There is no cure for SLE. However, various treatments are available that can help ease symptoms and minimise the impact SLE has on daily life.

## About mycophenolate

Mycophenolate is a type of drug called an 'immunosuppressant', which works by stopping the body's immune system from working normally. It is licensed in the UK to be used after someone has had an organ transplant, to try and stop the body from rejecting their new organ.

Treatments for systemic lupus erythematosus (or SLE for short) include non-steroidal anti-inflammatory drugs (or NSAIDs for short) such as ibuprofen, diclofenac and naproxen, corticosteroids (such as prednisolone), hydroxychloroquine, and immunosuppressants (such as azathioprine, methotrexate, cyclophosphamide, and mycophenolate). Some of these treatments, including mycophenolate, are not licensed specifically for treating SLE, and so their use would be 'off-label'.

## Summary of possible benefits and harms

### *How well does mycophenolate work?*

A large review of good-quality studies looked at how well mycophenolate (given with other drugs called corticosteroids) worked at treating lupus nephritis compared with other

immunosuppressant drugs (also given with corticosteroids). Lupus nephritis is a complication of systemic lupus erythematosus (or SLE for short; see [What is systemic lupus erythematosus?](#) for more information). The review found that mycophenolate worked as well as a drug called cyclophosphamide at improving symptoms and starting 'remission' (when the person has few or no symptoms). The review also found that mycophenolate was better than a drug called azathioprine for preventing flare-ups of lupus nephritis after remission.

Some other lower quality studies looked at how well mycophenolate works to treat other symptoms and complications of SLE that don't involve the kidneys. They showed that mycophenolate might work for treating SLE that affects the blood. However, it wasn't clear from the studies if it works for people with SLE affecting the skin.

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

The large review found that mycophenolate had fewer harmful side effects than cyclophosphamide. These side effects included ovarian failure (when the ovaries stop working properly), problems fighting infections and hair loss. However, diarrhoea was more common in people taking mycophenolate than in those taking cyclophosphamide.

In the other studies, diarrhoea, feeling or being sick, and infections were the most common side effects. These are very common side effects of mycophenolate and can affect more than 1 in 10 people who take this medicine.

People taking mycophenolate for any condition need to have regular blood tests. When people are taking mycophenolate their body will not be as good as normal at fighting infections, so they should try and keep away from anyone who is ill. People taking mycophenolate should tell their doctor if they have any sign of infection (such as a raised temperature, sore throat or cough) or any unexplained bleeding or bruising.

People taking mycophenolate may become more sensitive to the harmful effects of sunlight, and may have an increased risk of skin cancer. They should limit the amount of sunlight they get by wearing protective clothing and using high-factor sunscreen.

It is important that women do not become pregnant while taking mycophenolate, and contraception should be used before starting treatment, during treatment, and for 6 weeks after stopping treatment. This is because mycophenolate may cause miscarriage or harm unborn babies.

Mycophenolate should not be taken by women who are breast feeding.

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 mycophenolate.

## Prescribing mycophenolate

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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