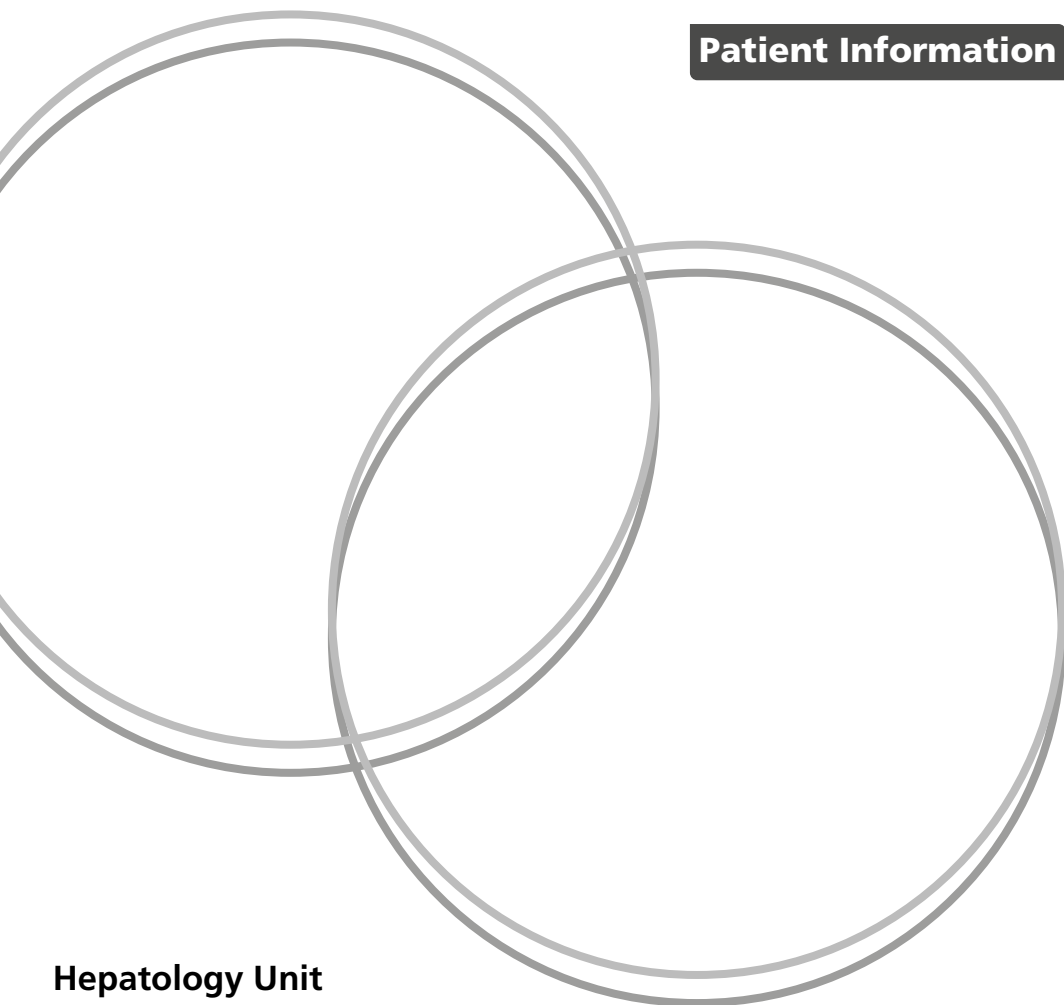


Mycophenolate mofetil in autoimmune liver disorders and liver transplant

Patient Information



Mycophenolate mofetil in autoimmune liver disorders and liver transplant

This leaflet answers some common questions patients ask about mycophenolate mofetil.

Further information can be found in the information leaflet supplied by the manufacturer or from your pharmacist, liver nurse specialist or doctor.

Why have I been started on this medicine?

Mycophenolate mofetil (also known as CellCept® and Myfenax®) is prescribed for patients diagnosed with AIH (autoimmune hepatitis) and IgG4-related disease affecting the liver/bile ducts and pancreas. These conditions are examples of an immune mediated (autoimmune) liver disorders. It is unlicensed for these indications but widely used in practice.

Autoimmune liver disorders can develop when your body's own immune system mistakenly attacks the cells in your liver causes damage. No one knows why this happens. If left untreated it can lead to cirrhosis (scarring of the liver), which has a higher risk of liver cancer.

AIH may have an inherited predisposition to the disease, which is finally triggered by something in the environment. We do not, however, know what the environmental trigger is (or triggers may be). 30-50% of people diagnosed with AIH have another autoimmune condition, such as thyroid disease, rheumatoid arthritis, ulcerative colitis or Type 1 diabetes. It is estimated that 15 to 25 per 100,000 people in Europe have AIH.

IgG4 related disease is a chronic-fibroinflammatory disorder affecting a wide range of organs. These are commonly the salivary glands, pancreas, bile duct and liver, aorta and retroperitoneum. It is a rare disease affecting an estimated 10 per 100,000 people.

Common symptoms associated with autoimmune liver disorders include fatigue, weight loss, nausea, abdominal pain, jaundice, dark urine. Because of related conditions, some people may have joint pains, diarrhoea and feel generally unwell. Most patients with well-controlled disease have no symptoms at all.

There is no cure for autoimmune liver disorders but there are effective treatments to control the disease and reduce the risk of progression including steroids, azathioprine and mercaptopurine

and mycophenolate. The main goal of treatment is to stop the liver inflammation by getting your immune system back under control. We can assess this with blood tests and imaging of the liver. Around 70% of patients will relapse within 12 months if treatment is withdrawn.

Mycophenolate mofetil is also prescribed for patients after a liver transplant, along with other medicines, to prevent rejection.

How does it work?

Mycophenolate mofetil suppresses inflammation and 'turns-off' the activity of the immune system. It is often referred to as a "steroid sparing agent" or "immunomodulator".

It is usually used in combination with a steroid e.g. prednisolone and if you are unable to tolerate azathioprine or mercaptopurine.

Reducing inflammation in the liver will improve your symptoms, improve your liver blood tests, reduce the degree of scarring, and help prevent long-term liver damage and liver failure.

How long does it take to work?

Mycophenolate mofetil can take several weeks to take effect unlike a steroid.

What dose do I take?

AIH, IgG4-RD, and Transplant: The dose of mycophenolate is usually between 500mg/day and 2g/day in two divided doses (e.g., 1g twice daily). The dose may be increased depending on response and side effects.

How do I take it?

Mycophenolate mofetil comes as tablets and capsules and is available in two different strengths, 250mg and 500mg. The dose should be taken with, or soon after, food. Swallow the tablets or capsules whole, do not crush, or break them. There is a liquid available for patients with swallowing difficulties.

How long will I be taking it?

For autoimmune liver disorders you will remain on mycophenolate for at least 2 years and for at least 12 months after normalization of blood tests (liver transaminases and IgG). Steroid-free monotherapy with mycophenolate (or azathioprine) is the goal of maintenance therapy. Patients can remain on mycophenolate for many years (>5 years), and the risks and benefits of continuing the medication is constantly assessed.

In liver transplant you will remain on treatment long- term to prevent rejection.

Do **not** stop taking it unless told to by your doctor.

What happens if I forget to take a dose?

If more than six hours has passed from the usual time you take your dose, then forget that dose and take the next dose at the normal time. Do not double the dose. If you take too much mycophenolate mofetil tell your GP or hepatology team as soon as possible.

What are the common side effects?

The main side effects of mycophenolate mofetil are gastro-intestinal disturbances such as diarrhoea, nausea or vomiting. Taking the total daily dose in divided doses throughout the day can reduce this. Diarrhoea caused by mycophenolate treatment may resolve after a few weeks if you continue with treatment.

As mycophenolate mofetil suppresses your immune system you can develop blood disorders leading to weakness or breathlessness, a susceptibility to infections, and a tendency to bruise easily. The risks are increased if you are also on other immunomodulators.

Occasionally mycophenolate mofetil may inflame the liver further or result in acute abdominal pain due to pancreatitis (inflammation of the pancreas gland) and can cause an increase in blood sugars.

As with any drug that affects the immune system, there may be an increased risk of lymphoma or skin cancer. You are advised to limit your exposure to sunlight and UV light by wearing protective clothing and using a high factor sunscreen. The use of sunbeds should be avoided.

Other reported side effects include hypersensitivity, fever, lethargy, headache, difficulty in sleeping, abdominal pain, hair loss, rash, and effects on your blood pressure.

See below for information about mycophenolate and pregnancy.

What do I do if I experience side effects?

If you experience any signs of illness or side effects such as unexplained bruising, bleeding, sore throat, fever, cough, shortness of breath, malaise, yellowness of the skin or whites of the eyes or severe itching (a sign of liver damage), contact your doctor or pharmacist immediately.

Do I need any special checks while on mycophenolate mofetil?

You will be under the specialist care of a hepatology consultant. When you are first diagnosed, you may require frequent outpatient appointments (every 2 weeks) so that we can adjust your medication and monitor your disease closely. Once your disease is well-controlled, your outpatient appointments and blood tests will become less frequent (every 3-6 months). It is important that you attend your appointments and have any tests that are recommended because they are vital to your care.

If you develop scarring of your liver (cirrhosis), you will have an ultrasound scan of the liver every six months. These ultrasound scans are important because people with cirrhosis have increased risk of liver cancer, and regular scans can help to detect liver cancer at an early and treatable stage.

Although the effects of mycophenolate mofetil on the blood (see above) are uncommon, it is important that you have regular blood tests to check for early signs of changes to the blood. It is recommended that this is done every 2 weeks for the first month then at 1 monthly intervals for 3-months and then at 3-monthly intervals.

You should also have your blood checked if you experience side effects such as a sore throat (see below) or if your dose changes. The blood tests can be done at the hospital or, with agreement of your GP, at your local surgery.

You should be offered hepatitis A and B vaccination if not protected and at risk.

If you have not had chicken pox before and come into personal contact with someone who has chickenpox or shingles, you must see a doctor as soon as possible.

We will do our best to keep the monitoring of your condition up to date. We strongly encourage you to become familiar with the tests you need, however, to ensure these tests happen when they should.

Does mycophenolate mofetil interfere with other medicines?

Most medicines are safe to take with mycophenolate mofetil, however, always check with your doctor or pharmacist first if you start any new medicines or herbal remedies, especially those that are not prescribed by a doctor.

It is safe to drink alcohol in moderation whilst on mycophenolate mofetil, but it may make diarrhoea and nausea worse. You will be advised not to drink alcohol if you have advanced fibrosis or liver cirrhosis.

You should avoid having 'live' vaccines whilst taking mycophenolate e.g., Mumps, measles and rubella (MMR), yellow fever, BCG, some Typhoid vaccines, Varicella vaccines. If you require travel vaccines or your doctor, nurse or pharmacist advise that you need a vaccine always tell the healthcare professional that you are taking prednisolone. Seasonal vaccination against influenza, Pneumococcal and COVID vaccines are also recommended for adults taking mycophenolate mofetil.

Is mycophenolate mofetil OK in pregnancy and breastfeeding?

Contraception for women taking mycophenolate mofetil

If you are a woman of childbearing age (12-55 years) you must always use two effective methods of contraception before starting treatment, whilst on treatment and for 6 weeks after stopping treatment. You should contact us as soon as possible if you think you may be pregnant due to ineffective contraception.

If you are a woman of childbearing age you must provide two negative pregnancy tests before starting treatment and must follow the contraception advice given to you by your doctor. We advise using birth control prior to treatment, as pregnancy tests may not reliably detect pregnancy during the first month. Your doctor may request more than one test to ensure you are not pregnancy before starting treatment.

Contraception for men taking mycophenoate mofetil

You must always use condoms during treatment when sexually active and for 90 days after you stop taking it. If you are planning to have a child, your doctor will talk to you about the risks and the alternative treatment options.

Female partners of male partners should use effective contraception during treatment and for 90 days after discontinuation.

Pregnancy and breastfeeding

If you think you may be pregnant or are planning to have a baby, you should contact the hepatology team for advice.

Mycophenolate mofetil causes a very high frequency of miscarriage (50%) and severe birth defects (23-27%) in the unborn baby. Birth defects which have been reported include anomalies of ears, eyes, face (cleft lip/palate), development of fingers, the heart, oesophagus (tube that connects throat with the stomach), kidneys and nervous system (for example spina bifida where the bone of the spine are not properly developed). Your baby may be affected by one or more of these.

Breastfeeding

You should not breastfeed if you are taking mycophenolate.

Where can I receive more information and support?

Hepatology pharmacist:

Tel: **01865 221 523**

Hepatology Nurse advice line:

Tel: **01865 222 057**

AIH Support:

Help for those affected by Autoimmune Hepatitis: AIH Support

British Liver Trust:

British Liver Trust Helpline: **0800 652 7330**
(10:00 to 15:00 Monday to Friday)

UK-AIH:

UK-AIH

Keep all medicines out of the reach of children.

Never give any medication prescribed for you to anyone else.

It may harm them even if their symptoms are the same as yours.

Further information

If you would like an interpreter, please speak to the department where you are being seen.

Please also tell them if you would like this information in another format, such as:

- Easy Read
- large print
- braille
- audio
- electronic
- another language.

We have tried to make the information in this leaflet meet your needs. If it does not meet your individual needs or situation, please speak to your healthcare team. They are happy to help.

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