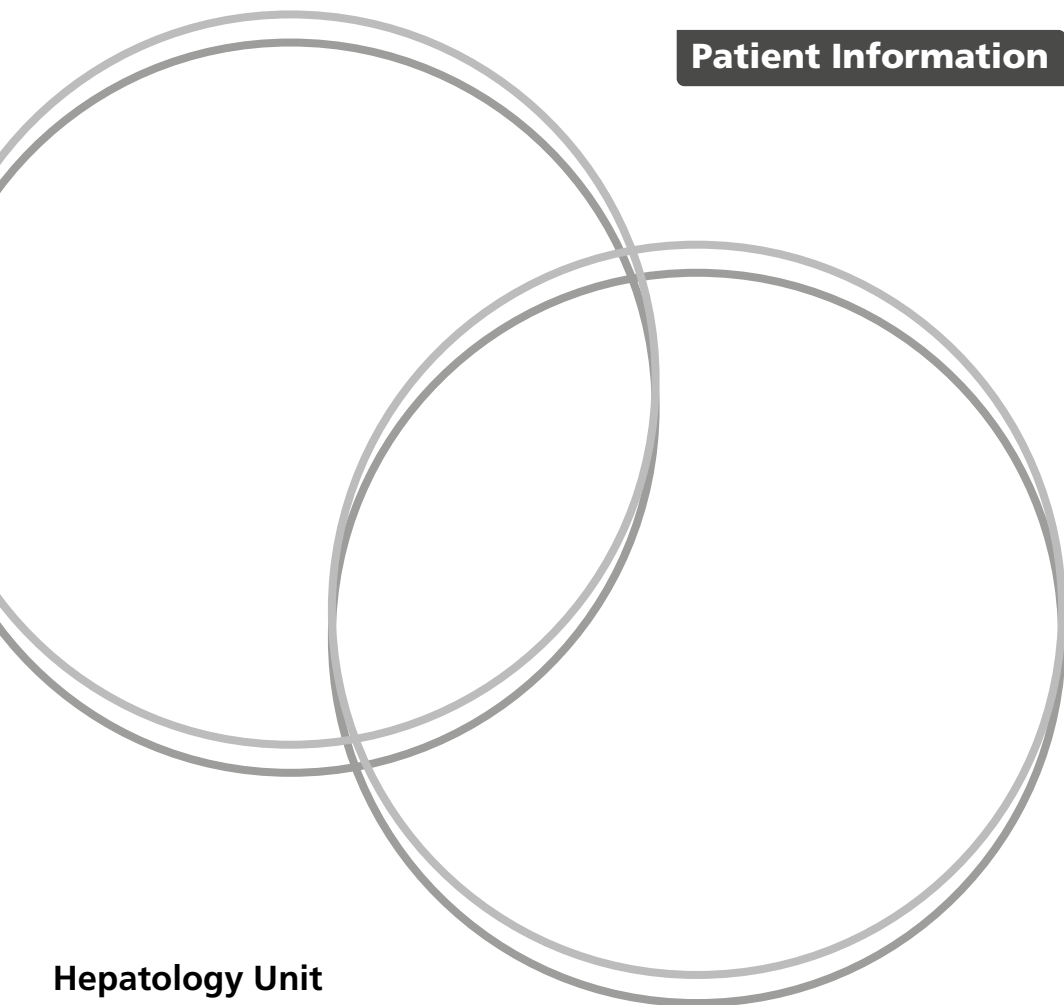


# Budesonide in autoimmune hepatitis (AIH)

**Patient Information**



# **Budesonide in autoimmune hepatitis (AIH)**

This leaflet answers some common questions patients ask about budesonide

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?**

Budesonide is a corticosteroid prescribed for patients diagnosed with AIH (autoimmune hepatitis) which is an immune mediated liver disorder.

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.

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 AIH but there are effective treatments including budesonide, prednisolone and azathioprine. 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 Around 70% of patients will relapse within 12 months if treatment is withdrawn.

## **How does it work?**

Budesonide is a manufactured steroid compound which suppresses inflammation in the liver.

All patients with AIH are initially treated with a high dose of steroid, either budesonide or prednisolone. The most appropriate corticosteroid option will be discussed with you.

Once inflammation in the liver is controlled, a longer-term immunosuppression tablet, usually azathioprine or mycophenolate is added, and the dose of steroid is reduced depending on your liver blood tests.

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?**

Budesonide works quickly and inflammation is usually controlled within a few weeks.

## **What dose do I take?**

For the induction of remission (i.e. normalization of blood tests) the recommended dose is 9mg/day. This can be taken as one capsule (containing 3 mg budesonide) three times daily (morning, midday and evening) or three capsules taken together in a single dose in the morning.

After achievement of remission the recommended dose is 6mg/day to be taken as a single dose in the morning or 3mg twice daily.

If the ALT or AST increase during maintenance treatment, the dose should be increased to 3 capsules per day (corresponding to a total daily dose of 9 mg budesonide) as described for induction of remission.

In patients tolerant to azathioprine, treatment for induction and maintenance of remission with budesonide should be combined with azathioprine.

## **How do I take it?**

Budesonide is available in different brands. Currently only Budenofalk® 3mg gastro-resistant capsules are licenced for AIH so you should ensure this is what you are taking.

The capsules should be swallowed whole, with a glass of water about half an hour before meals. Do not chew the capsules.

## **How long will I be taking it?**

Treatment for maintenance of remission in autoimmune hepatitis should be continued at least for 24 months. It might be stopped if biochemical remission is constantly maintained and if no signs of inflammation are present in a liver biopsy.

Budenoside should not be stopped abruptly but withdrawn gradually (tapering doses). Do not stop taking your budesonide unless your doctor tells you to, however well you may feel.

In patients with mild disease and intolerant to azathioprine and/or mycophenolate, budesonide will be continued at the lowest dose possible. In other patients, steroid-free monotherapy with azathioprine or mycophenolate is the goal of maintenance therapy.

For one year after you stop treatment, you must mention to anyone who treats you that you have taken steroids.

## **What happens if I forget to take a dose?**

If you miss a dose, just continue your treatment at the prescribed dosage. Do not take a double dose to make up for a forgotten dose.

If you have taken too much medicine on one occasion, take your next dose as prescribed. Do not take a smaller amount. Contact the hepatology team if you are worried.

## What are the common side effects?

Corticosteroids are hormones that are naturally produced by all of us to control such things as blood pressure and preparing our body for stress. To control inflammation within the liver, higher doses than those naturally produced are required. When the body is supplied with 'artificial' steroids, natural production decreases or stops (known as adrenal suppression). Most patients will experience some side effects while taking steroids.

Budesonide generally causes fewer side effects than equivalent doses of prednisolone taken by mouth but can still cause some of the typical side effects associated with corticosteroids that are absorbed into the bloodstream.

**Common side effects of steroids include** weight gain, reduced glucose tolerance, increase in blood sugar, high blood pressure, fluid retention in the tissues (e.g. swollen legs), irregular periods, unwanted body hair, impotence, abnormal laboratory findings (reduced adrenal function), red stripes on the skin (stretch marks), acne, indigestion, irritable stomach (dyspepsia), abdominal pain, increased risk of infection, muscle and joint pain, brittle bones (osteoporosis), headache, mood changes, such as depression, irritability or euphoria, rash

**This is not a complete list of side effects and others may occur. effects. Please refer to the manufacturer's leaflet for other side effects that have been reported and cautions for use**

## What do I do if I experience side effects?

If you become unwell or feverish, or meet anyone who has an infectious disease, consult your doctor promptly. If you are in an accident or need emergency treatment you may need a larger dose of steroids.

## **Do I need any special checks while on budesonide?**

You will be under the specialist care of a hepatology consultant. When you are first diagnosed, you may require weekly or similarly frequent outpatient appointments 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. 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 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.

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.

Long term budesonide use can increase the risk of osteopenia and osteoporosis. To minimize this, you should take a calcium and vitamin D supplement, and have regular bone DEXA scans every 1-2 years (or every 5 years if bone health is stable), which your specialist doctor will arrange.

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.

Steroids can increase the risk of skin cancer. You should avoid excessive exposure to sunlight and UV light, apply high factor sunscreen and wear protective clothing when outside. The use of sunbeds should be avoided.

**You will be given a red steroid card with budesonide. It is important that you always carry this with you and show it to anyone treating you. Make sure the information on the card is kept up to date.**

## Does budesonide interfere with other medicines?

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular:

- **cardiac glycosides** such as digoxin (medicines used to treat heart conditions)
- **diuretics** (to remove excess fluid from the body)
- **ketoconazole or itraconazole** (to treat fungal infections)
- **antibiotic** drugs used to treat infections (such as clarithromycin)
- **carbamazepine** (used in the treatment of epilepsy)
- **rifampicin** (for treating tuberculosis)
- **oestrogens** or oral contraceptives
- **cimetidine** (used to inhibit the production of acid in the stomach)

Some medicines may increase the effects of budesonide and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV).

If you take **cholestyramine** (for hypercholesterolemia and also used to treat diarrhoea) or **antacids or colesevelam** (for indigestion) in addition to budesonide, take these medicines **at least 2 hours apart**.

You should **not** drink **grapefruit juice** whilst you are taking this medicine as this can alter its effects.

It is safe to drink alcohol in moderation whilst on budesonide.

You should avoid having 'live' vaccines whilst taking mercaptopurine 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 budesonide. Seasonal vaccination against influenza, Pneumococcal and COVID vaccines are also recommended for adults taking budesonide.



## Is budesonide OK in pregnancy and breastfeeding?

Budesonide **is** considered safe. Corticosteroids can cross the placenta to the foetus but are rapidly inactivated by enzymes in the placenta. This means that the baby would only be exposed to very low levels of these medicines.

Budesonide **appears** in small amounts in human breast milk. To minimise exposure, you should ideally wait for 4 hours after taking this medication before breastfeeding. The benefit of breastfeeding outweighs any exposure.

You should not stop treatment if become pregnant or are planning a pregnancy without discussing with your doctor first. Sudden withdrawal of treatment can result in a flare of the condition.

# 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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Oxford University Hospitals NHS Foundation Trust  
[www.ouh.nhs.uk/information](http://www.ouh.nhs.uk/information)



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