

Alemtuzumab (Lemtrada)

This factsheet is about alemtuzumab, a disease modifying therapy (DMT) for relapsing multiple sclerosis (MS). At the end of this factsheet you'll find out where you can get more information on this drug, other drugs for MS and the benefits of early treatment.

This factsheet doesn't cover everything about this drug and shouldn't be used in place of advice from your MS specialist team. For more information speak to them and read the online information from the drug's makers (see the section **More information and support**).

What is alemtuzumab?

Alemtuzumab is a cancer drug that used to be called Campath. In 2013 it was given a licence to be used in the UK against relapsing MS. In 2014 the National Institute for Health and Care Excellence (NICE) gave the go ahead for the drug to be used on the NHS.

Alemtuzumab is pronounced: allem-TOOZER-mab.

Its brand name is **Lemtrada** (lem-TRAH-da).

Can I have this drug?

Because of the risk of serious side effects, you'll only be offered alemtuzumab if your MS is very active, especially if other DMTs haven't controlled it.

In February 2020, after reports of new, rare but serious side effects, the European Medicines Agency tightened the rules on who should have alemtuzumab. For details of these side effects go to **What side effects might I get?** What follows is who can have this drug now that the rules have changed.

You can take alemtuzumab if you have:

Across the UK:

- relapsing MS and, despite already taking a DMT, you've had a recent relapse, and MRI scans show new signs that your MS is active (you have new lesions)
- relapsing MS and you've had 2 or more relapses in the last year, and you have new lesions on your MRI scans (whether you're already on a DMT or not)

If you decide to take this drug, you and your neurologist must be happy to accept its higher risk and the need for extra blood and urine tests.

If you can have a drug also depends on whether the NHS where you live will pay for it. NHS guidelines on this tend to follow what NICE says.

You won't get this drug if:

- you're already on another DMT that's controlling your MS well. You can't take more than one DMT at a time
- you have progressive MS
- you have certain heart or circulation problems. This includes angina or stroke in the past, or high blood pressure that's not under control
- your blood doesn't clot like it should
- you have another auto-immune condition besides MS
- you have a serious infection

Alemtuzumab won't work if you don't get relapses. So you won't be offered it if you have primary or secondary progressive MS. But several drugs are being tested to see if they work against these non-relapsing, progressive types of MS.

You might not be able to take this drug if you have some other health conditions. So tell your MS specialist your full medical history, including any other health problems and medications you're taking.

You shouldn't be taking this drug if you're a woman trying to have a baby or not using contraception.

But if you've stopped taking alemtuzumab, then it's safe to get pregnant after four months have passed since your final dose (see the sections **What side effects might I get?** and **I want a child. Can I take alemtuzumab?**).

How do I take it?

You're given alemtuzumab in hospital through a drip (an 'infusion'). You sit in a chair or lie on a bed while it's pumped into your bloodstream through a needle into a vein in your arm or leg. Most people only need two infusions, spaced 12 months apart.

For the first infusion you go to hospital for five days in a row. Each day you have an infusion that takes about four hours. You might go home every day two hours after your infusion, or stay in hospital for your treatment.

You have the second treatment a year later, over three days in a row, again for about four hours each day. After the second treatment many people don't need to take this drug again. But between three people in ten and four in ten need a third or fourth infusion before the drug works.

How does it work?

Your immune system fights off infections. But with MS it attacks nerves in your brain and spinal

cord by mistake. This leads to inflammation and damage, especially to the coating that covers your nerves (myelin). This damage interferes with how signals travel along these nerves. Over time this affects your control over many parts of your body and causes symptoms of MS.

It's thought that much of the damage we see with MS is caused by white blood cells or 'lymphocytes', especially ones called T cells and B cells.

Alemtuzumab protects your nerves from damage by killing these immune cells before they get into your brain and spinal cord. Your immune system replaces these cells, but the new ones are less likely to attack your nerves.

Alemtuzumab does what other DMTs don't: it makes a permanent change to your immune system. The drug 'resets' it for good, so its positive effects can last years after your last dose.

How well does it work?

When DMTs are working well you have:

- fewer and less serious relapses
- fewer new or bigger 'lesions' (or 'plaques') in your brain and spinal cord (lesions can be seen on MRI scans)
- a slowdown in your disability getting worse

Like other DMTs, alemtuzumab works best the sooner you start it after you're diagnosed with MS. Taking it later can also have benefits, but it can't undo any permanent disability that you may already have.

DMTs can be split into three groups, according to how big their effect on MS can be.

High (they can work very well):

- **alemtuzumab (Lemtrada)**
- natalizumab (Tysabri)
- ocrelizumab (Ocrevus) when used for relapsing MS
- haematopoietic stem cell transplantation (HSCT)

Good (they can work well):

- cladribine (Mavenclad)

- dimethyl fumarate (Tecfidera)
- fingolimod (Gilenya)

Moderate (they can work fairly well):

- glatiramer acetate (Copaxone and Brabio)
- five different beta interferons (Avonex, Betaferon, Extavia, Rebif and Plegridy)
- teriflunomide (Aubagio)
- ocrelizumab (Ocrevus) when used for early primary progressive MS

The effectiveness of alemtuzumab is classed as 'high'



Relapses dropped by: **50–55% compared to beta interferons**

This means that in trials, on average, people saw a 50–55% drop in the number of relapses they had. This was compared to people who took beta interferons, a standard treatment for MS.

How many people stayed free of relapses when they took this drug?

Trial one

78% of people who took alemtuzumab in one trial stayed free of relapses for two years. They'd never taken a DMT before.



59% of people on beta interferon stayed free of relapses.



 = no relapses

Trial two

65% of people who took alemtuzumab in another trial stayed free of relapses over two years. They'd taken a DMT before that hadn't controlled their relapses.



47% of people on beta interferon stayed free of relapses.



Disability getting worse was slowed down by: **up to 42% compared to beta interferons**

This means that in one trial, on average, people saw a 42% drop in the risk of their disability getting worse. This was compared to people who took beta interferons.

How many people's disability didn't get worse when they took this drug?

Trial two

Disability didn't get worse over two years for 87% of people who took alemtuzumab.



Disability didn't get worse for 80% who took beta interferon.



 = disability didn't get worse

The figures here for relapses and disability come from two trials: CARE-MS I and CARE-MS II. Each trial lasted two years, following over a thousand people in total. In the first of these trials people taking alemtuzumab saw a 30% drop in the risk of their disability getting worse. This wasn't big enough to be seen as 'significant'. In other words, it could have happened by chance and not because of the drug.

Alemtuzumab might work much better for you than these average results - or it might not work as well.

Long-term effects: We don't have years of evidence about this drug's longer term effects. It's only been widely used since 2013. But a study of 87 people over seven years found it had a long lasting effect for the majority of people. For most their disability didn't get worse and relapses happened much less often. A larger study of 349 people over five years found similar results.

What side effects might I get?

Like all drugs, alemtuzumab can have side effects, but not everyone gets them. Not many people stop taking this drug because of side effects.

The more effective a DMT is, the more risk of serious side effects. Alemtuzumab is, along with natalizumab, the drug that controls MS best but with the biggest risk of side effects. You might get them for a few years after your last treatment. So you'll need to be aware of this, and have tests for four years after your last infusion (see **What tests will I need?**).

Alemtuzumab affects your immune cells that fight infections, so most people taking this drug get more infections. But these tend not to be serious and are relatively mild and easily treated. Up to four in ten people get a more serious side effect: a thyroid problem.

Alemtuzumab might harm unborn babies. If you're a woman, you'll need reliable contraception (like the 'pill' or condoms) while you're taking this drug. It's important to protect against pregnancy during each course of treatment and for four months afterwards. For more information on getting pregnant see **I want a child. Can I take alemtuzumab?**

Your neurologist, GP or MS nurse can give you advice about ways of dealing with side effects.

Very common side effects

(more than one in ten people get these)

- **less serious infections**
 - of your chest, throat, urinary tract and sinuses (the spaces around your nose)
 - most likely in the first month of treatment
- **reactions after your infusion** (most people get these)
 - including headache, rash, fever, feeling or being sick, hives (a skin rash), itching, reddening of the face and neck, and feeling tired
 - these are usually mild and short lived but can be serious for about three in 100 people
 - they can happen during the infusion or in the next 24 hours
- a drop in your white blood cells (lymphocytes) which fight infections. The drug is meant to make this happen, so almost everyone gets this
- other side effects could include sore throat, diarrhoea, pain in your joints, back, stomach, pain or tingling in your arms and legs, dizziness and trouble sleeping

Your doctor should give you steroids to reduce infusion reactions and medication to prevent 'cold sores'. You'll be monitored during the infusion and for two hours after.

Serious infections

This drug puts you at higher risk of getting a serious (but usually treatable) infection. In trials less than one person in 30 got a serious infection. Your neurologist may recommend extra tests or medicines to lower this risk.

Possible serious infections include;

- varicella zoster virus infections (shingles, chickenpox and types of inflammation of the brain). Only about one in 300 people got these in trials. If tests show you haven't already had this virus, you'll be vaccinated before you start alemtuzumab
- pneumonia
- genital warts caused by Human Papilloma Virus (HPV). Some types of HPV can cause pre-cancerous changes in a woman's cervix, so women on this drug should be checked once a year

- tuberculosis (TB) - your doctor may test you for this. Only about one in 300 people in trials got TB
- appendicitis
- it's not yet clear, but it's possible you might be more at risk of thyroid, blood or skin cancer

Tell your doctor straight away if you have signs of an infection such as fever, chills or swollen glands.

Autoimmune conditions

Alemtuzumab makes you more likely to get autoimmune conditions (when your immune system attacks your body by mistake).

The one seen most often is a problem with your:

thyroid

- up to four out of ten people get this
- your thyroid gland, in your neck, makes hormones and controls your metabolism (one thing this controls is how fast you burn calories)
- symptoms include sweating a lot, putting on or losing weight, your eyes swelling, nervousness, fast heartbeat, feeling cold, tiredness or constipation
- most people need life-long medication. Some need their thyroid taking out
- if you get a thyroid problem, you can carry on taking alemtuzumab

thrombocytopenia is something about two in 100 people get:

- this is when there aren't enough platelets in your blood, so you bleed too much
- if it's not treated, it may lead to serious health problems or death. But caught early, it's usually treatable

Symptoms of thrombocytopenia include:

- small red, pink or purple spots on your skin
- bruising easily
- bleeding that takes a long time to stop (such as from your gums or nose)
- coughing up blood
- blood in your wee or poo
- for women, bleeding between periods or having periods more often, or they're heavier or last longer

You often get no symptoms so you'll have regular blood tests to check for this. But call a doctor straight away if you have any of those symptoms.

Much rarer problems are:

kidney problems such as anti-GBM (anti-glomerular basement membrane) disease

- around one in 300 people get these problems.

Symptoms include:

- blood in your wee, turning it red or the colour of tea
- your legs or feet swell
- you cough up blood
- left untreated this can cause kidney failure, leading to dialysis, a transplant or death
- you'll get blood and urine tests each month to check for kidney problems but call a doctor straight away if you have symptoms

hepatitis (inflammation of the liver). About one in a thousand people get this

haemophilia (when your blood doesn't clot like it should). About one in 500 people got this in a trial of alemtuzumab

in recent years some people have developed **other rare autoimmune conditions**. Read more in the next section

rare conditions involving red or white blood cells

- these can be diagnosed from regular blood tests and treated

serious reactions when you have your infusion

- very rarely a person has a serious allergic reaction to alemtuzumab. This causes their mouth or throat to become swollen, with heart or breathing problems or a rash

More rare but dangerous side effects

In the last few years new but rare side effects have been seen with alemtuzumab. Within a week of their first infusion some people had:

- a stroke (around two in 5,000 people)
- heart attack (one in 5,000 people)
- blood vessels broke in their head or neck (around one in 5,000) or lungs (two in 5,000 people). This could cause someone to become

permanently disabled or even kill them.

Urgent warning signs

Because of these side effects, in early 2020 the European Medicines Agency announced new rules on who could have alemtuzumab. It said you should get medical help straight away if, in the days or months after your infusion:

- you have any chest pain or problems breathing while alemtuzumab is being given to you or in the next few days (these could be signs of a heart problem)
- you cough up blood or find it harder to breath (possible signs of bleeding in your lungs)
- your face drops on one side, you get a very bad headache, neck pain, weakness on one side of your body, or you find it harder to talk (these are signs of a stroke or damage to blood vessels in your brain)
- your skin or eyes turn yellow, your wee goes dark, you feel pain in your belly or you bleed or bruise easily (all signs of liver damage)
- you get a fever, swollen glands, bruising or rash (signs of a dangerous immune disorder called haemophagocytic lymphohistiocytosis).

Side effects: weighing up the risks of DMTs

Only you can decide what level of risk you're happy to take. You'll need to weigh up:

-  possible risks against the benefits you could enjoy
-  taking a DMT with fewer side effects but less impact, against a DMT with better results but maybe more serious side effects
-  the risk of not being treated.

This last point has recently become clearer. We now know that damage could be taking place in your brain between relapses, when it might seem nothing is happening with your MS. Before deciding, talk to others and get the information you need. Some ideas are in **More information and support**.

What tests will I need?

You'll have blood and tests on your wee to diagnose and treat infections or autoimmune problems, for example, with your thyroid. These tests happen before you start treatment, then every month and for four years after your last infusion. Your specialist can also arrange:

- a blood test to see if you're at risk of getting the varicella zoster virus (it causes chicken-pox and shingles). You'll need a vaccination if this test shows you've not already had this infection
- a blood test for TB
- for women, screening of the cervix (the neck of the womb) once a year

ABN guidelines say it's a good idea to have MRI scans to see how much difference the drug is making to your MS.

When should I stop taking this drug?

Most people don't need to take this drug again after the second time. Between three in ten and four in ten people will need to take it three or four times (very rarely a person will need a fifth infusion). Your neurologist might recommend you stop taking this drug if you have bad side effects or if after several courses it hasn't worked.

You'll need to stop taking alemtuzumab if your MS changes to secondary progressive MS. DMTs available now can't help people if they don't have relapses. But clinical trials are underway testing drugs for progressive, non-relapsing types of MS.

You'll also need to discuss with your neurologist stopping alemtuzumab if you're a woman thinking about getting pregnant (see next section for more details).

I want a child. Can I take alemtuzumab?

If you're a woman trying for a baby, you need to stop taking this drug and wait until the amount of it in your body drops to a safe level. The time this takes is called the 'washout period'. For alemtuzumab it's four months. Blood tests will check that the level of drug in your blood has dropped low enough.

Once you've had your very last infusion, and the drug has left your body four months later, you now have years during which it's safe to get pregnant.

It's safe to breastfeed four months after your last infusion but not while you're still taking the drug as it can get into your breast milk.

Men and women with MS who want to have a child should discuss this with their MS specialist. Talk to your neurologist if you're a woman and you think you may be pregnant.

More information and support

mssociety.org.uk/earlytreatment

On this web page you'll find more about treatment, a report on the evidence for early treatment, and links to our basic guide to DMTs and factsheets on other DMTs.

New guidelines say everyone should have a review of their MS and treatment with a specialist at least once a year. But if you're not happy with the treatment you're offered, find tips about what to do on this link: mssociety.org.uk/about-ms/treatments-and-therapies/getting-treatment-for-ms

Elsewhere on the MS Society site you'll find the latest updates on research into drugs for the different types of MS.

Patient information leaflets

Every DMT comes with detailed information about doses, how to store and take it, side effects and results from trials. Find the one for this drug at medicines.org.uk and search for 'alemtuzumab'

or 'Lemtrada'. The circle with 'PIL' on it has information written for patients. The circle with 'SPC' on it has information for doctors.

Your MS specialist team

Your neurologist, MS nurse and other members of your specialist team can give you information and support, as can your GP often. MS nurses, if you have one where you are, can be especially helpful if you need support taking a DMT.

mssociety.org.uk/forum

On this and other online forums you can talk to others thinking about treatment or already taking it.

About this resource

With thanks to Louise Coghlin and all the neurologists and people with MS who contributed to this factsheet.

Disclaimer: We have made every effort to ensure that the information in this publication is correct. We do not accept liability for any errors or omissions. Availability and prescribing criteria for drugs in various parts of the UK may change. Be sure to seek local advice from the sources listed.

Let us know what you think

If you have any comments on this information or on the work of the MS Society, please send them to resources@mssociety.org.uk

References

A list of references is available on request. Call 0300 500 8084.

Further information from the MS Society

Resources

Our award winning information resources cover every aspect of living with MS.

0300 500 8084

shop@mssociety.org.uk

mssociety.org.uk/publications

Helpline

The Freephone MS Helpline offers confidential emotional support and information for anyone affected by MS, including family, friends and carers.

Information is available in over 150 languages through an interpreter service.

0808 800 8000 (closed weekends and bank holidays)

helpline@mssociety.org.uk

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Together, we are strong enough to stop MS.

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This factsheet will be reviewed within three years of publication.

