

# Ocrelizumab (Ocrevus)

**This factsheet is about ocrelizumab, a disease modifying therapy (DMT) that treats both relapsing multiple sclerosis (MS) and early primary progressive 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 ocrelizumab?

Ocrelizumab is the first DMT that can treat relapsing MS and primary progressive MS. It was given a licence in 2018 to be used for both types in Europe, including the UK.

The National Institute for Health and Care Excellence (NICE) decide which drugs can be available on the NHS in England. In June 2018 it gave the go ahead for the drug to be used in England for relapsing MS. By the end of 2018 the rest of the UK had also made the drug available on the NHS for relapsing MS.

Since early 2020 the drug has also been recommended for use on the NHS in all the nations of the UK to treat early primary progressive MS.

This means it should soon be available on the NHS to people who meet the strict rules about who qualifies to get it. How easy it is to get will depend on how big demand is locally for the drug, for

appointments with neurologist and for MRI scans.

Ocrelizumab is pronounced: ock-ree-LEE-zoo-mab.

Its brand name is **Ocrevus** (Ock-REE-vuss).

## Can I have this drug?

Whether you'll be offered this or any other DMT depends on whether you qualify for it based on guidelines used by your neurologist. These come from NICE and the Association of British Neurologists and are based on a drug's Europe-wide licence.

In England there are also rules from NHS England about who can have the different DMTs and when. Scotland, Wales and Northern Ireland also have their own guidelines for many DMTs.

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

The rules about who can have ocrelizumab are different depending on whether your MS is relapsing or primary progressive MS.

On the next page you can see who can have ocrelizumab. First we look at which people with relapsing MS can have it. Then we look at who with primary progressive MS might get it.

## Relapsing MS

**In all parts of the UK:**

**You can take ocrelizumab for relapsing MS if you have:**

- active relapsing MS. This means you're having

relapses and MRI scans show new lesions (areas of nerve damage) in your brain or spinal cord

- **and** you qualify to take alemtuzumab (Lemtrada), but that drug isn't suitable for you

So, ocrelizumab can be given on the NHS to a small number of people with relapsing MS who qualify to have alemtuzumab (Lemtrada) – but they can't take that drug for some reason, or they have worries about its side effects and risks.

Who qualifies for alemtuzumab is quite complicated. You're most likely to be offered it if your MS is very active. This means you keep getting relapses or more lesions (whether or not you're taking another DMT). To see exactly who can get alemtuzumab, see our factsheet or web page on it at [mssociety.org.uk/alemtuzumab](https://mssociety.org.uk/alemtuzumab)

## Early primary progressive MS

**In all parts of the UK:**

**You can take ocrelizumab if you have:**

- early active primary progressive MS

The following all also need to be true:

- your MRI scans show signs of inflammation. In particular, you need a T1 MRI scan to show you have 'enhancing lesions' (this means a lesion has happened recently). Or you need two or more T2 MRI scans that show you have new or growing lesions
- you have a score on the Expanded Disability Status Scale (EDSS) between 3.0 and 6.5 (6.5 means you need two walking aids – such as canes or crutches – to walk about 20 metres without having a rest)
- you have early disease. This means that, if you're less disabled (EDSS score 5 or under), your MS started within the last 10 years. If you're more disabled (EDSS score over 5), it means it started within the last 15 years. A score of 5 means disability gets in the way of your daily activities but you can walk without an aid for 200 metres

## How do I know if I have 'early' primary progressive MS?

Your neurologist decides this based on the guidelines above that look at how long you've had symptoms, and how much disability it's caused you (especially your EDSS score).

The EDSS measures how much MS has affected you. It focusses on how well you can walk. Find it explained in more detail at [mssociety.org.uk/EDSS](https://mssociety.org.uk/EDSS)

As long as you meet all the conditions above, people of any age can be offered ocrelizumab.

## 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 primary progressive MS that's not classed as 'early'. That means you don't meet the conditions on page two about how long you've had MS, how badly it's affecting you, and what lesions can be seen on your MRI scans
- you have secondary progressive MS
- you've been using a wheelchair for at least six months (your EDSS score is 7 or over). This is because there's not enough evidence at the moment that any DMT will make enough difference to your MS
- you have an active case of hepatitis B (a liver infection)
- you have a very weakened immune system
- you have cancer

If you had cancer in the past, your doctor might decide to not give you this drug, or delay giving it to you. Tell your MS specialist your full medical history, including any other health problems and medications you're taking.

This drug shouldn't be taken if you're a woman and there's a chance you might become pregnant. Women taking ocrelizumab need to

make sure reliable contraception is used, such as condoms or 'the pill'.

For more on pregnancy see the sections **What side effects might I get?** and **I want a child. Can I take ocrelizumab?**.

## How do I take it?

Ocrelizumab is given in hospital through a drip (an 'infusion'). Before your infusion you're given steroids and antihistamine to reduce any reactions the infusion might trigger.

The infusion will take either two hours, or three and a half hours. Your MS Team can let you know which speed of infusion they'll use. Afterwards you're monitored for an hour.

You need to go to hospital for your infusion, but you don't need to stay overnight. For your first ever treatment you have two infusions two weeks apart. After that you have an infusion every six months.

During an infusion, ocrelizumab is slowly pumped into your bloodstream through a needle that goes into a vein, usually in your arm. You normally sit in a chair or lie on a bed during an infusion.

Any vaccinations you might need must be given to you at least six weeks before you start this drug (see 'vaccinations' in the section **What side effects might I get?**).

## How does it work?

Your immune system fights off infections. But with MS it attacks the nerves in your brain and spinal cord by mistake. This leads to inflammation and damage 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 a part of your immune system: your white blood cells or 'lymphocytes', especially ones called T cells and B cells. Ocrelizumab targets your B cells.

Your immune system protects you from disease by making antibodies that attach themselves to viruses and bacteria. This blocks them from spreading and doing more damage. It also marks them out for other parts of the immune system to destroy.

Ocrelizumab is a man-made ('monoclonal') antibody. The exact way that this drug works isn't understood but we know it sticks to your B cells and helps kill them. That way they can no longer attack and damage the myelin around your nerves.

## How well does ocrelizumab work?

When DMTs, including ocrelizumab, are working well you have:

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

As long as you meet the conditions you need to meet to get it, ocrelizumab - like other DMTs - 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.

The next page looks in detail at how well ocrelizumab works for both relapsing MS and early primary progressive MS.

**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)
- haematopoietic stem cell transplantation
- **ocrelizumab (Ocrevus) when used for relapsing MS**

**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**

## How well does it work for relapsing MS?

The effectiveness of ocrelizumab for treating relapsing MS is classed as 'high'



### Relapses dropped by **46-47%** compared to beta interferon

This means that in two trials, on average, people saw the number of relapses they had drop by almost half (by 46% in one trial, by 47% in the other). This was compared to people who took beta interferon, a standard treatment for MS.

### How many people stayed free of relapses when they took ocrelizumab?

Over 80% of people who took ocrelizumab in two trials stayed free of relapses for two years.



Over 70% of people on beta interferon stayed free of relapses.



 = no relapses

## Disability getting worse was slowed down by **40% compared to beta interferon**

This means that in two trials, on average, people saw a 40% drop in the risk of their disability getting worse. This was compared to people who took beta interferon. The drop was 43% in one trial and 37% in the other.

### How many people's disability didn't get worse when they took ocrelizumab?

Disability didn't get worse over six months for 92% of people who took ocrelizumab.



Disability didn't get worse for 88% of people who took beta interferon.



The figures here for relapses and disability come from two trials: OPERA I and OPERA II. Each trial lasted two years, following over 1,600 people in total. Ocrelizumab seemed to be a much better treatment for relapsing MS than beta interferon. It seems to work well but without the risk of serious side effects that come with some other MS drugs.

 = disability didn't get worse

Ocrelizumab might work much better for you than the average results we get from trials – or it might not work as well.

## Other effects

### Lesions

A lesion is an area of damage that MS causes to nerves in your brain or spinal cord. Ocrelizumab made people much less likely to get a certain type of lesion called a T1 lesion (a sign of new inflammation). Compared to people on beta interferon, people on ocrelizumab got 94-95% fewer of these lesions.

The drug also made people less likely to get T2 lesions. These are a sign of new inflammation or of damage that took place longer ago. People on ocrelizumab got fewer of these. And if they already had them, the lesions got smaller. The number of new or bigger lesions dropped by 77% in the first trial and by 83% in the second trial. This was compared to people on beta interferon.

### Your brain

Whether we have MS or not, our brains shrink a little each year as we get older. But in MS there's more of this shrinkage and it happens faster. Ocrelizumab slows this down more than beta interferon does.

## NEDA

NEDA stands for No Evidence of Disease Activity. This was something measured in the trials of ocrelizumab. It means that there are no signs that someone's MS is active – no new or growing lesions, no relapses, and disability has stopped getting worse.

In the two OPERA trials, over two years about half (48%) of people with relapsing MS who took ocrelizumab reached NEDA. Of those who took beta interferon, 25-29% reached NEDA. But these figures weren't statistically significant. This means these results may have happened by chance and not because of ocrelizumab.

## Long term effects

Since the first two years of the drug trials ended, people in them have been followed for several years more. The drug has carried on working for them for five years so far. But ocrelizumab is a new drug, so we don't have much evidence about whether it will keep working long term.

## How well does it work for early primary progressive MS?

The effectiveness of ocrelizumab for treating early primary progressive MS is classed as 'moderate'



## Disability getting worse was slowed down by: 25% compared to a placebo

This means that in one trial, on average, people saw a 25% drop in the risk of their disability getting worse over 24 weeks. This was compared to people who took a placebo, a dummy treatment with no drug in it.

This 'moderate' effect may not seem very big, but this type of MS has always been the hardest to understand and treat. This is the first drug to make a significant difference to primary progressive MS. In trials ocrelizumab has shown that, for people with early primary progressive MS, it could delay the need for a wheelchair by seven years.

## How many people's disability didn't get worse when they took ocrelizumab?

Disability didn't get worse over six months for 70% of people who took ocrelizumab.



Disability didn't get worse for 64% of people who took a placebo.



The figures here for how quickly disability got worse come from one trial: ORATORIO. It followed 732 people with primary progressive MS for two years. On average they'd had MS for six years.

## Other effects

### Lesions

Ocrelizumab made a certain type of lesion called T2 lesions smaller by 3%. They got 7% bigger in people who took the placebo. These lesions can be a sign of new inflammation or be left over from damage that took place longer ago.

### Walking speed

How fast people can walk got worse whether they were on ocrelizumab or placebo. But after two years overall the speed was 39% slower for ocrelizumab compared to 55% slower for the placebo.

### Arms, hands and fingers

Ocrelizumab slows down how fast MS causes disability in your upper limbs (arms, hands and fingers). A new UK study is now looking at this more closely. The study includes people who use a wheelchair.

### Your brain

Whether we have MS or not, our brains shrink a little each year as we get older. But in MS there's more of this shrinkage and it happens faster. Ocrelizumab slowed this down compared to the placebo.

Ocrelizumab might work much better for you than the average results we see in trials – or it might not work as well.

### Long-term effects

Ocrelizumab is a new drug so we don't have much evidence about its longer term effects. A new study is following people for longer and its results will be ready in 2021.

## What side effects might I get?

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

In trials there were no serious side effects like the ones you see with other, hard-hitting DMTs.

Ocrelizumab kills some of the cells in your immune system. But it doesn't target all types of your immune cells, so it still leaves you with enough protection against infections.

But taking this drug does mean you're more likely to get some (mostly mild) infections.

Ocrelizumab might harm unborn babies. If you're a woman who might get pregnant, you need to use reliable contraception (like the 'pill' or condoms) while you take this drug, and for 12 months after your last infusion of it.

If you become pregnant, you'll need to tell your neurologist straight away and stop taking this drug.

For more information on getting pregnant see the section **I want a child. Can I take ocrelizumab?**

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)

Up to one in four people have at least one fairly mild reaction to their infusion. These reactions can happen while you have the infusion or within 24 hours of it. They soon go away.

To make a reaction less likely, you're given steroids and antihistamines. You'll also be monitored during the infusion and for an hour afterwards.

**Infusion reactions** – these can include:

- hives (an itchy skin rash)
- your skin goes red, especially on your chest or face (flushing)
- feeling sick or dizzy
- headache
- tiredness
- you become short of breath
- a fast heartbeat
- low blood pressure
- fever (high temperature)
- pain or irritation in your throat, or your throat swells up

These reactions are most likely when you have your first infusion. They get less likely with infusions afterwards. If you have a reaction, the infusion might have to be slowed down or stopped until it goes away.

Up to five people out of every 200 might have a more serious reaction to their infusion. If that happens, they'll not be able to carry on taking this drug.

### Infections

You may be more likely to come down with infections. Colds and flu are the most common ones. About half of people in the trials got these.

Other common infections (up to one in ten people get these) are:

- herpes infections (including cold sores and shingles)
- infection of your sinuses (the spaces behind your cheeks, forehead and nose)
- chest infections like bronchitis and coughs
- stomach and bowel infections (gastroenteritis)
- infections like sore throats and tonsillitis
- viral infections
- skin infections

### Effects on your blood

Another side effect that's often seen is a drop in your levels of immunoglobulin M and G. These are specific proteins in your blood that help protect you against infections.

Also common is neutropenia. This is when you have low levels of a type of white blood cell that fight off infections. A fever can be a symptom of this.

## More serious side effects

### Cancer

In trials more people taking this drug got cancer, especially breast cancer. But the number was still within the normal range. So it's not clear if this is a side effect of the drug. The drug's makers are monitoring this risk.

### PML

Progressive multifocal leukoencephalopathy (PML) is a rare but very serious brain infection. You're at risk if you've been infected with the JC virus. Over half of people with MS have this virus.

Our immune system normally stops it causing us problems. But when you take some DMTs there's a very small risk the virus becomes active.

Signs of PML are similar to MS symptoms or a relapse: clumsiness, poor balance, weakness on

one side of your body or with your arms and legs, or changes in your speech, eyesight or memory and thinking.

PML is most likely to happen with the drug natalizumab (Tysabri). There's not yet been a case of it in someone with MS where doctors think ocrelizumab caused it. But we might see cases in the future. This is because a very similar form of the drug called rituximab has caused PML in a small number of people taking it for other health problems.

Ocrelizumab has only been used for a few years. We'll get a better understanding of possible long-term side effects by monitoring people with MS on this drug as time goes by.

### Vaccinations

You must not have a vaccination while taking ocrelizumab if it's a 'live' (or 'live attenuated') vaccine. That means the vaccine has in it a small, living piece of the virus it's meant to protect you against. Ocrelizumab makes your immune system work a bit less well, so a live vaccine could trigger the infection it's meant to protect you against.

Any vaccinations you need should be done at least six weeks before treatment with ocrelizumab starts. Vaccinations you might need include ones against tetanus, hepatitis, polio and human papillomavirus (HPV). You can still have the annual flu jab while being treated with this drug, but talk to your neurologist first.

In **More information and support** you'll find where you can get a full list of all possible side effects and other information about this drug.

### 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. If you get relapses, we now know that damage could be taking place in your brain even if you're not having 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?

Before you start this drug you'll have one or maybe two MRI scans of your brain. Six weeks before your first infusion you'll be vaccinated against hepatitis, tetanus, polio and the Human papillomavirus (HPV). HPV causes warts and some cancers.

Before you take ocrelizumab you need to be tested to see if you have the liver infection hepatitis B – or if you've had it in the past.

If you have an active hepatitis B infection, you won't be able to start ocrelizumab as it might cause a more severe case of it. If you've had this infection in the past, ocrelizumab could make it active again. So you'll need special monitoring to check this isn't happening. Or you might be given a drug to stop the hepatitis coming back.

You'll need no special monitoring or tests while you take this drug. But your neurologist will probably want you to have an MRI scan once a year to see if the drug is working.

## When should I stop taking this drug?

Ocrelizumab is meant to be taken long term. If it's controlling your MS well and side effects aren't a problem, it's hoped you'll be able to take it for years.

If you have bad side effects, or the drug isn't controlling your MS, your neurologist will recommend you stop taking ocrelizumab. If you've been taking it because you have relapsing MS, your neurologist can switch you to another DMT. Switching drugs usually only happens after you've taken a drug for six months.

If you've been taking this drug for early primary progressive and need to stop taking it, unfortunately there are no other DMTs at the moment that you can take instead.

You'll need to stop taking ocrelizumab if:

- you're a woman and you find yourself pregnant, or you decide you want to get pregnant (see next section for more details)
- you develop a serious infection. Your neurologist might decide that it's best to stop taking ocrelizumab for a while
- you have relapsing MS and this changes to secondary progressive MS and you stop having relapses. DMTs available now can't help people with progressive MS if they don't have relapses or active inflammation. Trials are underway testing other drugs to treat progressive, non-relapsing types of MS
- your EDSS score reaches 7 and you've been using a wheelchair for at least six months. If this happens, you usually stop taking your DMT. Your neurologist will discuss with you whether it's worth carrying on taking your DMT.

## I want a child. Can I take ocrelizumab?

Ocrelizumab might harm unborn babies. So you shouldn't be taking this drug if:

- you're a woman and you find yourself pregnant
- you're already pregnant (or think you might be)
- you want to breastfeed

If you're a woman trying for a baby, you need to wait for at least 12 months since your last infusion of this drug before you get pregnant.

Ocrelizumab might pass into your breast milk. So, if you're a mother who wants to breastfeed, you shouldn't feed this way while taking this drug.

Men and women with MS who would like to have a child should discuss this with their neurologist. Women who think they may be pregnant should tell their neurologist straight away.

Women who've just had a baby are more likely to have a relapse. So it's recommended they restart their DMT soon after giving birth.

## More information and support

[mssociety.org.uk/earlytreatment](https://mssociety.org.uk/earlytreatment)

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

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 here: [mssociety.org.uk/about-ms/treatments-and-therapies/getting-treatment-for-ms](https://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.

Helpline: 0808 800 8000

## 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](https://www.medicines.org.uk) and search for 'ocrelizumab' or 'Ocrevus'. 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](https://www.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 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](mailto: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](mailto:shop@mssociety.org.uk)

[mssociety.org.uk/publications](https://www.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](mailto:helpline@mssociety.org.uk)

The MS Society is here to make life better for people with MS, through research, campaigning and support.

We can see a future where nobody needs to worry about MS getting worse.

We believe that, together, we can stop MS.

[mssociety.org.uk/stop-ms](https://mssociety.org.uk/stop-ms)

## Contact us

### MS Helpline

Freephone 0808 800 8000

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### Online

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Lines are open Monday to Friday, 9am – 5pm
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Please make cheques payable to the 'MS Society.'

### FS29

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This factsheet will be reviewed within three years of publication.

