

Teriflunomide (Aubagio)

This factsheet is about teriflunomide, 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 teriflunomide?

Teriflunomide is a drug that was given a licence in 2013 in the UK for use against relapsing MS. In 2014 the National Institute for Health and Care Excellence (NICE) gave the go ahead for it to be made available on the NHS.

Teriflunomide is pronounced: terry-FLOO-nee-mide.

Its brand name is **Aubagio** (oh-BAH-jee-oh).

Can I have this drug?

Teriflunomide is recommended for the treatment of 'active' relapsing MS, defined in guidelines as two or more relapses in the last two years. But more and more MS specialists define 'active' MS as one recent relapse and/or signs on MRI scans that MS is active. These signs include new 'lesions' (areas of damage) in your brain.

So you can take teriflunomide if you have:

In Scotland, Wales and Northern Ireland:

 relapsing MS and you've had a recent relapse and/or MRI scans show new signs that your MS is active (you have new 'lesions') In England you can have this drug if:

you've had two relapses in the last two years

Whether you'll be offered this drug depends on if you qualify for it based on guidelines used by your neurologist.

These come from the Association of British Neurologists (ABN) and NICE. In England there are rules from NHS Enland about who can have the diferent DMTs and when. Scotland, Wales and Northern Ireland also have their own guidelines for many DMTs.

It 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
- your MS is 'highly active' or severe and getting worse fast (you're having frequent relapses despite being on a DMT)
- you have progressive MS

Teriflunomide won't help you if you don't get relapses with your MS. 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 for people with these non-relapsing, progressive types of MS.

You might not be able to take this drug if you have some health conditions. So tell your neurologist 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 or man trying to have a baby or not using contraception (see the section **What side effects might I get?**).

How do I take it?

Teriflunomide is a tablet you take once a day.

How does teriflunomide 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, 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.

We don't know exactly how teriflunomide works, but it reduces inflammation. It seems to block certain cells made by your immune system that fight infections.

These are white blood cells ('lymphocytes') called T cells. They kill viruses and bacteria but in MS they're thought to cause damage to the brain and spinal cord.

Teriflunomide makes it harder for T cells to reproduce themselves. So there are fewer of these cells to cause inflammation.

The drug doesn't affect other cells in your immune system. So your body can still fight off infections, though not quite as well as before.

How well does it work?

When DMTs, including teriflunomide, 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, teriflunomide 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 you may already have.

DMTs can be split into three groups, according to how big their effects 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)

 ocrelizumab (Ocrevus) when used for relapsing MS*

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

*ocrelizumab is new, so it's too soon to be sure how to rank it when it's used for relapsing MS. It'll either be 'high' or 'good', so we've put it under both.

The effectiveness of teriflunomide is classed as 'moderate'



Relapses dropped by: 31% compared to a placebo

This means that in a trial, on average, people saw a 31% drop in the number of relapses they had. This was compared to people who took a placebo, a dummy pill with no drug in it.

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

57% of people who took teriflunomide stayed free of relapses over two years.



46% of people who took the placebo stayed fee of relapses.



Disability getting worse was slowed down by: 30% compared to placebo

This means that in one trial, on average, people saw a 30% drop in the risk of their disability getting worse. This was compared to people who took a placebo.

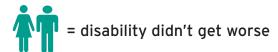
How many people's disability didn't get worse when they took this drug?

Disability didn't get worse over two years for 80% of people who took dimethyl fumarate.



Disability didn't get worse for 73% of people who took the placebo.





The evidence about the benefits of teriflunomide here comes from the TEMSO trial in 2011 that followed over a thousand people for two years.

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

www.mssociety.org.uk

What side effects might I get?

Like all drugs, teriflunomide 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. Teriflunomide (along with beta interferons and glatiramer acetate) is one of the DMTs that is least effective at controlling MS but has the lowest risk of serious side effects.

Teriflunomide might harm unborn babies. If you're a woman, you'll need reliable contraception (such as the 'pill' or condoms) while you're taking this drug. This is also true after you stop taking it until the drug has left your body. This can take up to two years unless you take a medicine that speeds this up to under three months. For more information on getting pregnant see I want a child. Can I take teriflunomide?

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 one of these)

- feeling sick
- diarrhoea
- hair thinning (hair grows back after six months)
- increase in some liver enzymes (this doesn't cause symptoms)

While taking teriflunomide you may get headaches. You might get infections more easily or infections may be worse than usual. This happens to up to one in ten people.

This is because this drug lowers how many white blood cells you have that fight infections. But the drug doesn't affect other parts of your immune system, so you can still fight off infections but not as well as before.

Infections you might get include:

- flu (fever or flu-like symptoms)
- infections of your throat or sinuses (the spaces behind and above your nose)
- urinary tract infection or cystitis

- bronchitis
- diarrhoea, stomach upsets or being sick
- 'cold sores'
- tooth infections
- fungal foot infections

1-2% of people get numbness or tingling in their arms or legs (peripheral neuropathy).

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?

Before you start this drug and while you're taking it, you'll have your blood pressure taken. Blood tests will check your liver and how many white blood cells and blood platelets you have.

You should have these tests every two weeks for the first six months, then every two months after that. As part of your treatment, ABN guidelines say it's a good idea to have MRI scans to see how well the drug is controlling your MS.

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Helpline: 0808 800 8000

When should I stop taking this drug?

Teriflunomide is meant to be taken long term. It's quite new so there's not a lot of evidence about taking it for a long time. But in a study of people on it for around eight years it kept working and had no new risks that we didn't already know about.

If it's controlling your MS well and side effects aren't a problem, you should be able to take it for many years.

Your neurologist might recommend you stop taking teriflunomide and switch to another DMT. This can happen if you have bad side effects, or the drug isn't controlling your MS. Switching drugs usually only happens after you've taken a drug for six months.

You'll need to stop taking teriflunomide if:

- your MS changes to secondary progressive MS. DMTs available now can't help people if they don't have relapses. But many clinical trials are underway testing drugs for people with progressive, non-relapsing types of MS
- you pick up a serious infection (you may have to stop taking the drug until it's gone)

If you're a woman thinking about getting pregnant, you need to stop taking this drug. Discuss how you do this with your neurologist.

Small amounts of this drug can be passed into a woman on sperm. So men taking this drug should get advice from their neurologist about the risk of unprotected sex with female partners, or if they want to father a child. Teriflunomide can also lower a man's sperm count (see next section for more details).

I want a child. Can I take teriflunomide?

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

- you're a woman trying to get pregnant (or man wanting to father a child)
- 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 talk to your neurologist about coming off this drug. Before you can safely get pregnant, you'll need to wait until the amount of the drug in your body drops to a safe level. The time this takes is called the 'washout period'. For teriflunomide this can be up to two years unless you take medication to speed this up to three months. Blood tests can check that the level of the drug in your blood has dropped low enough.

If you want to keep taking a DMT during your pregnancy, you should switch to a different drug.

Women who've just had a baby are more likely to have a relapse. So if you stop teriflunomide, it's recommended you restart it soon after giving birth.

This drug can pass into your breast milk. If you're a mother who wants to breastfeed, you shouldn't feed this way while taking teriflunomide (and for however long your neurologist recommends after you stop taking it).

Men and women with MS who want a child should discuss this with their neurologist. Women who think they may be pregnant should also talk to a neurologist.

Teriflunomide can lower sperm counts in men who take it. Small amounts of the drug can travel on sperm into a woman's body, which, if she then became pregnant, could damage the unborn baby. So men should get advice from their neurologist about the risk of unprotected sex with female partners, or if they want to father a child.

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 here: 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 'teriflunomide' or 'Aubagio'. 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
- 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.

We're the MS Society. Our community is here for you through the highs, lows and everything in between. We understand what life's like with MS.

Together, we are strong enough to stop MS

Contact us

MS National Centre

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MS Helpline

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This factsheet will be reviewed within three years of publication.

