

Fingolimod (Gilenya)

This factsheet is about fingolimod, 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 fingolimod?

Fingolimod is a drug that was first given a licence to be used against relapsing MS in the UK in 2011. In 2012 the National Institute for Health and Care Excellence (NICE) gave the go ahead for it to be used on the NHS. It was the first DMT you take as a tablet.

Fingolimod is pronounced finn-GOLLY-mod. Its brand name is **Gilenya** (pronounced jill-EN-ee-yer).

Can I have this drug?

Fingolimod is recommended for the treatment of 'highly active' relapsing MS. 'Highly active' means that, even though you're taking a DMT, you're still getting relapses and MRI scans show signs that your MS is active. These signs include new 'lesions' (areas of damage) in your brain. You can also have fingolimod if you're not on a DMT but are having frequent relapses and/or new lesions can be seen on scans of your brain.

Who can have this drug is different depending on where in the UK you are. These people can have fingolimod:

In Scotland and Wales

- People with 'highly active relapsing remitting MS' who have failed to respond to a DMT
- People who have 'rapidly evolving severe relapsing remitting MS'. This means they've had two or more disabling relapses in one year and an increase in lesions as shown on two MRI scans

In England and Northern Ireland

- People with 'highly active relapsing remitting MS'. This means they're getting the same or an increased number of relapses despite treatment with beta interferon (Avonex, Rebif, Betaferon, Extavai or Plegridy), glatiramer acetate (Copaxone), dimethyl fumarate (Tecfidera) or teriflunomide (Aubagio).

Across the UK

People on natalizumab (Tysabri) at high risk of developing a serious brain infection called PML might be switched to fingolimod

The 2015 guidance from the Association of British Neurologists (ABN) suggests that fingolimod can also be the first drug that's given to people if they have 'highly active' relapsing MS. For people in England new rules from NHS England allow fingolimod to be your first DMT if you have 'rapidly evolving severe relapsing remitting MS' and you're not suitable for natalizumab.

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 ABN and NICE. In England there are 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.

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

A trial in 2014 showed that fingolimod won't help people with primary progressive MS. You also won't be offered it if you have 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 health conditions. So tell your neurologist your full medical history, including any other health problems and medications you're taking.

If you're a woman trying to have a baby, or not using contraception, you should discuss with your neurologist if there's any risk this drug might pose to your baby if you become pregnant (see the section **What side effects might I get?**).

How do I take it?

Fingolimod is a tablet you take once a day. You're given your first dose in hospital and you'll be monitored for at least six hours to check for problems. After this first dose you take all other doses at home.

How does it work?

Your immune system fights off infections. But with MS it attacks parts of 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.

Immune cells called white blood cells or 'lymphocytes', especially ones called T and B cells, are thought to be responsible for much of the damage MS causes. Fingolimod sticks to these cells, stopping many of them leaving your lymph nodes where they're made.

This means far fewer of them reach your brain and spinal cord where they would attack the myelin coating of your nerves. Fingolimod doesn't affect other cells in your immune system,

so your body can still fight off infections, though not quite as well as before.

This drug might also directly stop nerves from being damaged or help repair them.

How well does it work?

When DMTs, including fingolimod, 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, fingolimod 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 effect 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 fingolimod is classed as 'good'



Relapses dropped by: 54% compared to placebo

This means that in a trial, on average, people saw a 54% 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?

Trial one

70% of people on fingolimod stayed free of relapses over two years.



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



Trial two

83% of people in another trial who took fingolimod stayed free of relapses over one year.



70% of people who instead took beta interferon, a standard MS treatment, stayed free of relapses.



 = no relapses

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

This means that in a 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 82% of people who took fingolimod.



Disability didn't get worse for 76% of people who took a placebo.



 = disability didn't get worse

In another trial 94% of people on fingolimod saw no worsening of their disability over one year compared to 92% of people who took beta interferon. This difference isn't big enough to be statistically significant (it might have happened by chance, not because of the drug).

These figures come from a clinical trial called FREEDOMS, which followed 1,280 people for two years, and a trial called TRANSFORMS, which followed around 1,000 people over one year.

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

What side effects might I get?

Like all drugs, fingolimod 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. Fingolimod is somewhere between the less effective drugs with fewer side effects (beta interferons and glatiramer acetate) and the harder hitting drugs with more serious ones (alemtuzumab and natalizumab).

There's no evidence that fingolimod harms unborn babies. But, if you're a woman on fingolimod who might get pregnant, until we know more about the drug's possible risks, it's recommended you use effective contraception (condoms or 'the pill'). This is also true for two months after you stop taking this drug.

If you get pregnant on fingolimod, you should speak to your MS doctor straight away about stopping this drug. For more information on getting pregnant see **I want a baby. Can I take fingolimod?**

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

The most common side effects (which more than one in ten people get)

- more chance of infections, eg, flu or sinusitis (pressure or pain in the spaces around your nose)
- diarrhoea
- back pain
- cough
- headache
- raised levels of liver enzymes in your blood (this causes no symptoms)
- feeling weak or tired

Side effects that could be more serious

heart

- your heart beat may temporarily slow down or become irregular, especially after your first dose
- up to one in ten people get an irregular or slow heart beat but it only caused symptoms (dizziness, tiredness and palpitations) for less than one in a 100 people in one large trial
- you're given your first dose of fingolimod in hospital and monitored for at least six hours after taking it to check for problems
- changes to your heart beat are normally nothing to worry about. Usually an irregular heartbeat goes back to normal within a day and a slow heart beat returns to normal within a month

infections

- while on fingolimod, and for up to two months after you stop taking it, you may get infections more easily. These may be worse than usual. Up to one in 10 people might get infections, eg, 'cold sores' or shingles
- this is because this drug cuts your number of white blood cells that fight infections
- if you get a serious infection, your MS specialist might decide that it's best to stop taking fingolimod for a while
- see a doctor straight away if you have fever, body aches or chills as they could be early signs of a serious infection

eyes

- you could get a serious, but not common, eye condition called macular oedema
- fluid builds up at the back of your eye, causing blurred vision, blind spots, problems seeing colours or details
- between one in 100 and one in 200 people get macular oedema, mostly in the first three to four months of treatment. It's more likely if you have diabetes
- you'll have your eyes checked a few months after you start fingolimod
- macular oedema normally gets better if you stop taking the drug

brain

- fingolimod has an extremely small risk of progressive multifocal leukoencephalopathy (PML), a serious viral brain infection (see box)

PML: a very rare but serious side effect

Fingolimod can increase your chances of getting a rare brain infection called PML (progressive multifocal leukoencephalopathy). PML often leaves people seriously disabled or kills them. PML is caused by the JC virus. Over half of people with MS have this virus. Our immune system normally stops it causing us problems but fingolimod changes the immune system, allowing this virus to become active.

The risk is extremely small. As of February 2018 19 people around the world have definitely or probably got PML from taking fingolimod out of 225,000 people across the world taking it. This works out as a risk of less than one in 10,000.

A blood test will show if you have the JC virus. If you have it, your health care team will tell you what to look out for and what to do if you notice signs of PML. These signs include clumsiness, weakness on one side and changes in your speech, vision or memory and thinking.

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. 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?

Fingolimod can change your heart beat for a while. So this will be monitored for at least six hours after your first dose with a painless test called an electrocardiogram (ECG).

Your eyes will be checked for macular oedema three to four months after you start fingolimod. If you've ever had inflammation of the eye called uveitis or you're diabetic, you'll be checked more often.

Before, during and after treatment with fingolimod you'll have blood tests to check your liver, blood pressure and how many white blood cells you have. You might also have tests on your lungs and heart.

Before you begin this drug you should have a blood test to see if you've any protection from the virus that causes chickenpox and shingles.

If you've had chickenpox in the past, you should still be naturally protected against this virus. If not, you'll need to be vaccinated and wait four to six weeks before starting fingolimod.

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.

When should I stop taking this drug?

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

One study followed people on the drug for nearly five years and found it carries on working and doesn't have any new risks that we didn't already know about.

There might come a time when your neurologist thinks you should switch from fingolimod 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 fingolimod 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 people with progressive, non-relapsing forms of MS
- you develop a serious infection. Your neurologist might decide it's best to stop taking fingolimod for a while

If you're a woman thinking about getting pregnant, you should stop taking this drug. Discuss how you do this with your neurologist. (see next section for information).

I want a child. Can I take fingolimod?

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

- you're a woman trying to get pregnant
- you're already pregnant (or think you might be)
- you want to breastfeed

If you're a woman trying for a baby, doctors recommend you stop taking fingolimod before you get pregnant. You need to wait until the amount of it in your body drops to a safe level. The time this takes is called the 'washout period'. For fingolimod it's two months. Blood tests can check that the level of the drug in your blood has dropped low enough.

If you get pregnant, you should stop taking this drug. Talk to your neurologist about maybe switching to another DMT during your pregnancy.

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.

Fingolimod 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 (and for two months after you stop taking it).

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 also talk to a neurologist.

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 'fingolimod' or 'Gilenya'. 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

🖥 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

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

☎ 0300 500 8084

✉ info@mssociety.org.uk

MS Helpline

☎ 0808 800 8000 (closed weekends and bank holidays)

✉ helpline@mssociety.org.uk

Online

💻 www.mssociety.org.uk

📘 /mssociety

🐦 /mssocietyuk

MS Society Scotland

☎ 0131 335 4050

✉ msscotland@mssociety.org.uk

MS Society Northern Ireland

☎ 028 9080 2802

✉ nireception@mssociety.org.uk

MS Society Cymru

☎ 0300 500 8084

✉ mscymru@mssociety.org.uk

We rely on the generosity of people like you to fund our vital work. If you would like to make a donation, you can do so by:

- Calling us on: **0300 500 8084**.
Lines are open Monday to Friday, 9am – 5pm
- Visiting us at: **mssociety.org.uk/donate**
- Posting your donation to: MS Society, National Centre, 372 Edgware Road, London NW2 6ND.
Please make cheques payable to the 'MS Society.'

FS23

© Multiple Sclerosis Society. May 2016 (b)

This factsheet will be reviewed within three years of publication.