Dimethyl fumarate (Tecfidera)

This factsheet is about dimethyl fumarate, 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.

What is dimethyl fumarate?

In 2012 a trial showed that a drug called BG-12 used for psoriasis, a skin problem, also worked against MS. In 2013 it was given the new name of dimethyl fumarate (DMF) and a licence to be used in the UK to treat 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.

Dimethyl fumarate is pronounced: dye-METH-ul FUME-er-ayt.

Its brand name is Tecfidera (teckfer-DAIR-ah).

Can I have this drug?

Dimethyl fumarate 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 dimethyl fumarate if you have:

- 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’)

Whether you’ll be offered this drug depends on if you qualify for it based on guidelines used by your MS specialist. These come from the Association of British Neurologists (ABN) and NICE. 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:

- your MS has gone beyond ‘active’ (it’s now ‘highly active’ or severe and getting worse fast)
- 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

Dimethyl fumarate 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 now 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 MS specialist 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 MS specialist 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?).

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).
How do I take it?
Dimethyl fumarate is a tablet you take twice a day. Taking it with food may help reduce some of its side effects.

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, 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 dimethyl fumarate works, but studies show it may help to prevent the inflammation that causes damage in your brain and spinal cord. It also seems to dampen down the reaction of your immune system and protect nerves from damage.

How well does it work?
When DMTs, including dimethyl fumarate, 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

The effectiveness of dimethyl fumarate is classed as ‘good’

Relapses dropped by: 53%
This means that in one trial, on average, people saw a 53% 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
73% of people who took dimethyl fumarate stayed free of relapses for two years.

Like other DMTs, dimethyl fumarate 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)

Good (they can work well):
• dimethyl fumarate (Tecfidera)
• fingolimod (Gilenya)

Moderate (they can work fairly well):
• glatiramer acetate (Copaxone)
• five different beta interferons (Avonex, Betaferon, Extavia, Rebif and Plegridy)
• teriflunomide (Aubagio)
54% of people who took the placebo stayed free of relapses.

Trial two

71% of people who took dimethyl fumarate in another trial stayed free of relapses over two years.

59% of people who took the placebo stayed free of relapses.

Disability getting worse was slowed down by: 38%

This means that in one trial, on average, people saw a 38% 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?

Trial one

Disability didn’t get worse over two years for 84% of people who took dimethyl fumarate.

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

In the second trial 87% of people who took dimethyl fumarate saw no worsening of their disability compared to 83% of people who took a placebo. This difference isn’t big enough to be statistically significant (it might have happened by chance, not because of the drug).

The figures here on relapses and disability come from two studies: the 2012 DEFINE study over two years of 1,234 people, and another 2012 study of 1,417 people over two years called CONFIRM. This last study came up with similar results to the first, including (for the twice a day dose people normally take) a 44% drop in relapse rate and 21% reduction in disease progression compared to a placebo.

Dimethyl fumarate 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, dimethyl fumarate 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. Dimethyl fumarate 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).

Some DMTs might harm unborn babies but if a woman becomes pregnant while taking dimethyl fumarate this DMT doesn’t seem to be risky. If you’re a woman who might become pregnant ask your MS specialist for advice about this risk and whether you need to use reliable contraception (condoms or ‘the pill’) while on this drug. For more information on getting pregnant see I want a child. Can I take dimethyl fumarate?

At the beginning of treatment side effects are common but tend to become less as time goes on. Your MS specialist, GP or MS nurse can give you advice about ways of dealing with side effects.

The most common side effects (in one study up to four out of ten people had one or more of the following)

- flushing and feeling hot (around a third of people get this). Aspirin can help
- diarrhoea or upset stomach (half get this to begin with but only around one in ten still have this three months later)
- feeling sick
- headache
- a drop in your white blood cells (a part of your immune system). This could leave you more open to infections but in one trial people got about the same number of infections as people not taking the drug. This drug could leave you open to a very rare brain infection, PML (see box below).

Itchy skin or a rash is another common side effect. Side effects usually go away after a few weeks (in one study after the first month only one person in 20 still had them). Taking dimethyl fumarate with food helps reduce side effects. If you think you might have a serious infection talk to your doctor straight away.

Up to one in 100 people can have a serious allergic reaction to dimethyl fumarate. Stop taking the drug straight away and call a doctor if you become flushed and get swelling of your face, lips, mouth or tongue and/or wheezing, have difficulty breathing or shortness of breath.

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.

PML: a very rare but serious side effect

Dimethyl fumarate can increase your chances of getting a rare brain infection, 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 dimethyl fumarate changes the immune system, allowing this virus to become active.

The risk is extremely small. As of May 2016 only four cases have been seen in over 100,000 people across the world taking dimethyl fumarate. 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 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.
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 like 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?

Dimethyl fumarate may affect your kidneys and liver and how many white blood cells you have. So you’ll have blood tests before and during treatment to check for this.

As part of your treatment ABN guidelines say you should have MRI scans to see how well the drug is controlling your MS.

When should I stop taking this drug?

Dimethyl fumarate, like all DMTs except one, is meant to be taken long term. If this drug is controlling your MS well and side effects aren’t a problem, you should be able to take it for years. A study of people taking it for six years and longer shows it keeps working and has no risks that we didn’t already know about.

Your specialist might recommend you switch from dimethyl fumarate 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 dimethyl fumarate 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 forms of MS.

You’ll also need to discuss with your MS specialist whether to stop taking dimethyl fumarate if you’re a woman thinking about getting pregnant (see the next section for more details).

I want a child. Can I take dimethyl fumarate?

The latest research suggests that dimethyl fumarate could be safe for a woman to take when she’s pregnant. Talk to your neurologist if:

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

Women who’ve just had a baby are more likely to have a relapse. So if you do stop taking this drug in order to get pregnant it’s recommended you restart it soon after giving birth.

If you stop you should wait until the amount of the drug in your body drops to a certain level. The time this takes is called the ‘washout period’. There’s no set period for dimethyl fumarate although doctors might recommend a month or less. Blood tests will check that the level of drug in your blood has dropped low enough.

If you’re a mother who wants to breastfeed ask your MS specialist for advice about feeding this way while taking dimethyl fumarate (and after you stop taking it).

Men and women with MS who would like to have a child should discuss this with their MS specialist. Talk to your MS specialist if you’re a woman and you think you may be pregnant.
More information and support

www.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 in our Talking about treatments checklist, also on this link.

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 www.medicines.org.uk and search for ‘dimethyl fumarate’ or ‘Tecfidera’. 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.

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 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, or you can complete our short online survey at www.surveymonkey.com/s/MSresources

References

A list of references is available on request, and all cited articles are available to borrow from the MS Society library (there may be a small charge). Contact the librarian on 020 8438 0900, or visit www.mssociety.org.uk/library

Further information from the MS Society

Library

For more information, research articles and DVDs about MS contact our librarian.

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🌐 www.mssociety.org.uk/library

Resources

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

📞 020 8438 0999
✉️ 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 (weekdays 9am–9pm)
✉️ helpline@mssociety.org.uk
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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**

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