Information Sheet

MS Ireland
THE MULTIPLE SCLEROSIS SOCIETY OF IRELAND

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Tecfidera (dimethyl fumarate)

This information sheet refers to a drug for the treatment of adult patients with relapsing remitting multiple sclerosis

What is Tecfidera?

Tecifidera (dimethyl fumarate or DMF) is a drug for treating relapsing- remitting multiple sclerosis (RRMS). Biogen Idec (who manufactures Avonex and Tysabri) is the manufacturer.

(**Of Interest:** Fumaderm, a therapeutic for the treatment of psoriasis in Germany, includes dimethyl fumarate as one of the active ingredients. Fumaderm has more than 14 years of post-marketing experience and approximately 100,000 patient years of use.)

How does Tecfidera work?

Tecfidera seems to work by stopping the body's defence system from damaging your brain and spinal cord. This may also help to delay future worsening of your MS.

How is Tecfidera administered?

Tecfidera is licensed for twice daily dosing. The starting dose is 120 mg twice a day. After 7 days, the dose is increased to the recommended dose of 240 mg twice a day.

Swallow each capsule whole, with some water. Do not divide, crush, dissolve, suck or chew the capsule as this may increase some side effects.

Take Tecfidera with food – it may help to reduce some of the very common side effects

What are the side effects from taking Tecfidera?

Serious effects

Allergic reactions - these are uncommon and may affect *up to 1 in 100 people*
Reddening of the face or body (*flushing*) is a very common (*may affect more than 1 in 10 people*) side effect. However, if you become flushed **and** get any of these signs:

- swelling of the face, lips, mouth or tongue
- wheezing, difficulty breathing or shortness of breath

Very common side effects

These may affect *more than 1 in 10 people:*

- reddening of the face or body feeling warm, hot, burning or itchy *(flushing)*
- loose stools *(diarrhoea)*
- feeling sick *(nausea)*
- stomach pain or stomach cramps

Common side effects

These may affect *up to 1 in 10 people:*

- inflammation of the lining of the intestines (*gastroenteritis*)
- being sick *(vomiting)*
- indigestion (*dyspepsia*)
- inflammation of the lining of the stomach (*gastritis*)
- gastrointestinal disorder
- burning sensation
- hot flush, feeling hot
- itchy skin (*pruritus*)
- rash
- pink or red blotches on the skin (*erythema*)

Common side effects, which may show up in your blood or urine tests

- low levels of white blood cells (*lymphopenia, leucopenia*) in the blood. Reduced white blood cells could mean your body is less able to fight an infection. If you have a serious infection (such as pneumonia)
- proteins (*albumin*) in urine
- increase in levels of liver enzymes (*ALT, AST*) in the blood

If you get any side effects, **talk to your doctor or pharmacist.**

When is Tecfidera likely to become available?

Tecfidera has now been approved by the European Commission (EC) for the treatment of adult patients with relapsing- remitting multiple sclerosis (RRMS) (1). However the product is not yet available in Ireland. The NCPE assessment and subsequent approval typically takes up to 225 days and commercial availability of Tecfidera is anticipated thereafter.

What does MS Ireland say in relation to Tecfidera?

MS Ireland welcomes Tecifera as an additional treatment option for people with MS. The advent of new and innovative oral therapies for the treatment of MS is an important step in the management of MS as a condition. Any and all strides made by pharmaceutical companies and researchers play a crucial role in the development of better treatments to decrease the instances of relapse and limit disease progression.

Reference

1. Tecfidera SPC (January 2014)