Dimethyl fumarate (Tecfidera): risk of infection – get regular blood tests, report unusual symptoms

Key messages:
- A person taking dimethyl fumarate (brand name: Tecfidera) died of a rare brain infection (progressive multifocal leukoencephalopathy).
- Dimethyl fumarate can reduce the number of certain white blood cells which can leave you vulnerable to infection.
- Read the information leaflet in the packet before taking the medicine.
- Keep taking your medicine as prescribed.
- Make sure you have your full blood count checked every 6 to 12 months.
- Speak to your prescriber if you:
  - think your multiple sclerosis is getting worse
  - notice any new symptoms (see below)
  - have a long-lasting infection or fever

What is dimethyl fumarate and what does it do?
Dimethyl fumarate (brand name: Tecfidera) is a medicine used to treat relapsing-remitting multiple sclerosis. Multiple sclerosis is a disease where the covers of the nerves in the brain and spinal cord are inflamed and damaged.

What is the new safety information about dimethyl fumarate?
A person taking dimethyl fumarate died of progressive multifocal leukoencephalopathy (PML) in Germany in October 2014. PML is a rare disease involving damage and inflammation of brain tissue caused by a viral infection. This is the only known case of PML in someone taking dimethyl fumarate for multiple sclerosis.

It has been known for some time that dimethyl fumarate can reduce the number of certain white blood cells. Because white blood cells are an important part of the body’s defence system, not having enough of them can make a person vulnerable to infection. The person described above had been taking dimethyl fumarate for 4.5 years and had a very low level of white blood cells for more than 3.5 years. This might be why they developed PML.

What should I do if I am taking dimethyl fumarate?
- Read the information leaflet in the packet before taking the medicine. Keep taking your medicine as prescribed.
- Make sure you have your full blood count (which includes white blood cells) checked every 6 to 12 months.
- Speak to your prescriber if you think your multiple sclerosis is getting worse or if you notice any new symptoms.
- Speak to your prescriber if you think you have a long-lasting infection or fever.

What are the symptoms of PML?
The symptoms of PML can be similar to the symptoms of multiple sclerosis. Speak to your prescriber if you believe your multiple sclerosis is getting worse or if you notice any new or unusual symptoms.

Reporting side effects
Please report any suspected side effects to any medicine or vaccine to the Yellow Card Scheme via the website (www.mhra.gov.uk/yellowcard) or by calling the free phone line (0800 731 6789). By reporting side effects you can help provide more information on the safety of medicines.