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Dimethyl fumarate Mylan (*dimethyl fumarate*)

An overview of Dimethyl fumarate Mylan and why it is authorised in the EU

What is Dimethyl fumarate Mylan and what is it used for?

Dimethyl fumarate Mylan is a medicine used to treat multiple sclerosis (MS), a disease in which inflammation damages the protective insulation around nerves (demyelination) as well as the nerves themselves. It is used in adults with a type of MS known as relapsing-remitting MS, where the patient has flare-ups of symptoms (relapses) followed by periods of recovery (remissions).

Dimethyl fumarate Mylan contains the active substance dimethyl fumarate and is a 'generic medicine'. This means that Dimethyl fumarate Mylan contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Tecfidera. For more information on generic medicines, see the question-and-answer document here.

How is Dimethyl fumarate Mylan used?

Dimethyl fumarate Mylan can only be obtained with a prescription and treatment should be started under the supervision of a doctor experienced in treating MS.

Dimethyl fumarate Mylan is available as capsules to be taken by mouth with food. The dose is 120 mg twice a day for the first seven days, after which it is increased to 240 mg twice a day. The dose may be reduced temporarily in patients experiencing side effects of flushing and gastrointestinal (stomach and gut) problems.

For more information about using Dimethyl fumarate Mylan, see the package leaflet or contact your doctor or pharmacist.

How does Dimethyl fumarate Mylan work?

In MS, the immune system (the body's natural defences) malfunctions and attacks parts of the central nervous system (the brain, spinal cord and the optic nerve of the eye), causing inflammation that damages the nerves and the insulation around them. The active substance, dimethyl fumarate, is thought to work by activating a protein called 'Nrf2' that regulates certain genes that produce 'antioxidants' involved in protecting cells from damage. Dimethyl fumarate has been shown to reduce inflammation and modulate the activity of the immune system.

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How has Dimethyl fumarate Mylan been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Tecfidera, and do not need to be repeated for Dimethyl fumarate Mylan.

As for every medicine, the company provided studies on the quality of Dimethyl fumarate Mylan. The company also carried out studies that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Dimethyl fumarate Mylan?

Because Dimethyl fumarate Mylan is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Dimethyl fumarate Mylan authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Dimethyl fumarate Mylan has been shown to have comparable quality and to be bioequivalent to Tecfidera. Therefore, the Agency's view was that, as for Tecfidera, the benefits of Dimethyl fumarate Mylan outweigh the identified risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Dimethyl fumarate Mylan?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Dimethyl fumarate Mylan have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Dimethyl fumarate Mylan are continuously monitored. Suspected side effects reported with Dimethyl fumarate Mylan are carefully evaluated and any necessary action taken to protect patients.

Other information about Dimethyl fumarate Mylan

Dimethyl fumarate Mylan received a marketing authorisation valid throughout the EU on 13 May 2022.

Further information on Dimethyl fumarate Mylan can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/dimethyl-fumarate-mylan. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 05-2022.