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Dimethyl fumarate Accord (*dimethyl fumarate*)

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

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

Dimethyl fumarate Accord 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 and adolescents from 13 years of age 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 Accord contains the active substance dimethyl fumarate and is a 'generic medicine'. This means that Dimethyl fumarate Accord contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Dimethyl fumarate Accord is Tecfidera. For more information on generic medicines, see the question-and-answer document here.

How is Dimethyl fumarate Accord used?

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

Dimethyl fumarate Accord is available as capsules to be taken by mouth, twice a day with food. During the first week of treatment a lower dose is taken, which is then increased from the second week. 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 Accord, see the package leaflet or contact your doctor or pharmacist.

How does Dimethyl fumarate Accord work?

In MS, the immune system (the body's natural defences) attacks and damages the protective insulation around the nerves and the nerves themselves in the brain, spinal cord and the optic nerve of the eye. The active substance in this medicine, 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.

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Dimethyl fumarate has been shown to reduce inflammation and modulate the activity of the immune system.

How has Dimethyl fumarate Accord 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 Accord.

As for every medicine, the company provided studies on the quality of Dimethyl fumarate Accord. 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 Accord?

Because Dimethyl fumarate Accord 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 Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Dimethyl fumarate Accord 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 Accord 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 Accord?

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

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

Other information about Dimethyl fumarate Accord

Dimethyl fumarate Accord received a marketing authorisation valid throughout the EU on 22 April 2024.

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

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