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Dimethyl fumarate Teva (*dimethyl fumarate*)

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

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

Dimethyl fumarate Teva 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 children 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 Teva is a 'generic medicine'. This means that Dimethyl fumarate Teva 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.

Dimethyl fumarate Teva contains the active substance dimethyl fumarate.

How is Dimethyl fumarate Teva used?

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

Dimethyl fumarate Teva 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 flushing and gastrointestinal (stomach and gut) problems as side effects.

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

How does Dimethyl fumarate Teva 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 in this medicine, dimethyl fumarate, is thought to work by activating a protein called 'Nrf2'. This protein regulates certain genes

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producing 'antioxidants' that help protect cells from damage. Dimethyl fumarate has been shown to reduce inflammation and modulate the activity of the immune system.

How has Dimethyl fumarate Teva 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 Teva.

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

Because Dimethyl fumarate Teva 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 Teva authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Dimethyl fumarate Teva has been shown to have comparable quality and to be bioequivalent to the reference medicine. Therefore, the Agency's view was that, as for Tecfidera, the benefits of Dimethyl fumarate Teva 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 Teva?

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

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

Other information about Dimethyl fumarate Teva

Dimethyl fumarate Teva received a marketing authorisation valid throughout the EU on 12 December 2022.

Further information on Dimethyl fumarate Teva can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Dimethyl-fumarate-Teva.

This overview was last updated in 12-2022.