



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/127784/2022  
EMA/H/C/005955

## Dimethyl fumarate Polpharma (*dimethyl fumarate*)

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

### What is Dimethyl fumarate Polpharma and what is it used for?

Dimethyl fumarate Polpharma 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 Polpharma contains the active substance dimethyl fumarate and is a 'generic medicine'. This means that Dimethyl fumarate Polpharma 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 Polpharma used?

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

Dimethyl fumarate Polpharma 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 Polpharma, see the package leaflet or contact your doctor or pharmacist.

### How does Dimethyl fumarate Polpharma 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.

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

An agency of the European Union



## **How has Dimethyl fumarate Polpharma 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 Polpharma.

As for every medicine, the company provided data on the quality of Dimethyl fumarate Polpharma. 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 Polpharma?**

Because Dimethyl fumarate Polpharma 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 Polpharma authorised in the EU?**

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

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

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

## **Other information about Dimethyl fumarate Polpharma**

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

Further information on Dimethyl fumarate Polpharma can be found on the Agency's website: [ema.europa.eu/medicines/human/EPAR/dimethyl-fumarate-polpharma](https://ema.europa.eu/medicines/human/EPAR/dimethyl-fumarate-polpharma). Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 05-2022.