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Tecfidera *(dimethyl fumarate)*

An overview of Tecfidera and why it is authorised in the EU

What is Tecfidera and what is it used for?

Tecfidera 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).

Tecfidera contains the active substance dimethyl fumarate.

How is Tecfidera used?

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

Tecfidera 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 Tecfidera, see the package leaflet or contact your doctor or pharmacist.

How does Tecfidera 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
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

What benefits of Tecfidera have been shown in studies?

Tecfidera has been shown to reduce the risk of relapses and how often they occur in adults with relapsing-remitting MS. In a main study involving 1,234 adults, the proportion of patients who experienced a relapse over the course of two years was significantly lower with Tecfidera treatment than with placebo (a dummy treatment): 27% versus 46%.

In a second main study involving 1,417 adults, patients were given Tecfidera, placebo or another medicine for MS, glatiramer acetate. This study showed Tecfidera to be more effective than placebo in reducing the number of relapses over the course of two years: the number of relapses per patient per year was around 0.2 with Tecfidera compared with 0.4 with placebo. The number of relapses per patient per year for glatiramer acetate was 0.3.

A main study involving 150 children and adolescents aged 10 to 17 years compared the effects of Tecfidera with interferon beta-1a (another MS medicine). After two years of treatment, around 13% of children taking Tecfidera had no new or newly enlarged lesions (damaged areas) in the brain, compared with around 3% of children in the interferon group. Since there were very few 10- to 12-year-old children in the study, it was not possible to determine the safety of Tecfidera in these young patients, and use of the medicine is therefore recommended from the age of 13.

What are the risks associated with Tecfidera?

The most common side effects with Tecfidera (which may affect more than 1 in 10 people) are flushing (reddening of skin) and gastrointestinal problems (such as diarrhoea, nausea, and pain in the abdominal area). These side effects tend to start early during treatment, usually in the first month, and may continue intermittently throughout treatment.

Tecfidera must not be used in patients who have or might have progressive multifocal leukoencephalopathy (PML), a serious brain infection that has been associated with some MS medicines.

For the full list of side effects and restrictions with Tecfidera, see the package leaflet.

Why is Tecfidera authorised in the EU?

Tecfidera has been shown to be effective in reducing the risk of relapses in adults with relapsing-remitting MS and how often they occur, and in reducing the risk of new lesions appearing or existing lesions becoming larger in children and adolescents from 13 years of age. The main risks identified with Tecfidera are considered to be manageable and include flushing and gastrointestinal problems (the most common side effects), as well as reduced levels of white blood cells, and protein in the urine.

The European Medicines Agency therefore decided that Tecfidera's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Tecfidera?

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

As for all medicines, data on the use of Tecfidera are continuously monitored. Side effects reported with Tecfidera are carefully evaluated and any necessary action taken to protect patients.

Other information about Tecfidera

Tecfidera received a marketing authorisation valid throughout the EU on 30 January 2014.

Further information on Tecfidera can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/tecfidera.

This overview was last updated in 05-2022.