EMA/204830/2013
EMEA/H/C/002601

EPAR summary for the public

Tecfidera

dimethyl fumarate

This is a summary of the European public assessment report (EPAR) for Tecfidera. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Tecfidera.

For practical information about using Tecfidera, patients should read the package leaflet or contact their doctor or pharmacist.

What is Tecfidera and what is it used for?

Tecfidera is a medicine that contains the active substance dimethyl fumarate. It is used to treat multiple sclerosis (MS), a disease in which inflammation destroys the protective sheath around the nerves. It is used specifically 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).

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 oral capsules (120 and 240 mg) to be taken 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 problems.

How does Tecfidera work?

In MS, the body's immune system malfunctions and attacks parts of the central nervous system (the brain and spinal cord), causing the inflammation that damages the nerve sheaths. The active substance, dimethyl fumarate, is thought to work by activating a protein called 'Nrf2' that regulates

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

certain ‘antioxidant’ genes involved in protecting cells from damage. Dimethyl fumarate, has been shown in studies to reduce the inflammation and modulate the activity of the immune system.

What benefits of Tecfidera have been shown in studies?

Tecfidera has been shown to reduce the number of relapses in patients with relapsing-remitting MS and to reduce the number of patients who have them.

In a main study involving 1,234 patients, 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 patients, patients were given Tecfidera, placebo or another medicine, 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.

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. For the full list of all side effects reported with Tecfidera, see the package leaflet.

Why is Tecfidera approved?

Tecfidera has been shown to be effective in reducing the number of relapses in patients with relapsing-remitting MS and in reducing the number of patients who have relapses during treatment. 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 Agency’s Committee for Medicinal Products for Human Use (CHMP) therefore concluded that Tecfidera’s benefits are greater than its risks and recommended that it be approved for use in the EU.

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

A risk management plan has been developed to ensure that Tecfidera is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Tecfidera, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, a number of studies with Tecfidera are planned or underway to provide further long-term safety data and to monitor the medicine.

Other information about Tecfidera

The European Commission granted a marketing authorisation valid throughout the European Union for Tecfidera on 30 January 2014.

The full EPAR for Tecfidera can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Tecfidera, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2014.