



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Vumerity (*diroximel fumarate*)

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

What is Vumerity and what is it used for?

Vumerity is a medicine used to treat adults with a type of multiple sclerosis (MS) known as relapsing-remitting MS. MS is a disease in which 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. In relapsing-remitting MS, the patient has flare-ups of symptoms (relapses) followed by periods of recovery (remissions).

Vumerity contains the active substance diroximel fumarate.

How is Vumerity used?

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

Vumerity is available as capsules to be taken by mouth. The dose is 231 mg (one capsule) twice a day for the first seven days, after which it is increased to 462 mg (two capsules) twice a day. The dose may be reduced temporarily in patients experiencing side effects of flushing (reddening of the skin) or gastrointestinal (stomach and gut) problems.

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

How does Vumerity work?

The active substance in Vumerity, diroximel fumarate, is similar to another authorised MS medicine, Tecfidera, which contains the active substance dimethyl fumarate. Both medicines are converted into the same active form, monomethyl fumarate, in the body.

This active form is thought to work by increasing the effect of a protein called 'Nrf2'. Nrf2 controls specific genes that produce antioxidants (substances that can prevent damage to cells from highly reactive molecules called 'free radicals'). Activation of Nrf2 and the resultant increased production of antioxidants appears to help control the activity of the immune system and reduce damage to the brain and spinal cord in patients with MS.

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What benefits of Vumerity have been shown in studies?

Ten clinical studies involving healthy volunteers looked at how diroximel fumarate (Vumerity) was absorbed, modified and removed from the body. Three of these studies included a comparison with dimethyl fumarate (Tecfidera). Two further studies looked at the effects of Vumerity in patients with MS, including one comparing the risk of gastrointestinal problems in patients given Vumerity or Tecfidera. The studies showed that 462 mg of diroximel fumarate and 240 mg of dimethyl fumarate rapidly converted to a similar amount of the active form, monomethyl fumarate, after intake. Based on these studies, it is expected that these doses of diroximel fumarate and dimethyl fumarate will be similar in terms of efficacy and safety in patients with relapsing remitting MS.

Two main studies have previously shown that dimethyl fumarate reduces the risk of relapse and how often they occur in patients with relapsing-remitting MS.

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 dimethyl fumarate treatment twice a day than with placebo (a dummy treatment): 27% versus 46%.

In a second main study involving 1,417 patients, patients were given dimethyl fumarate, placebo or another medicine for MS, glatiramer acetate. This study showed dimethyl fumarate 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 (which is equivalent to one relapse every five years) with dimethyl fumarate compared with 0.4 with placebo. The number of relapses per patient per year with glatiramer acetate was 0.3.

What are the risks associated with Vumerity?

The most common side effects with Vumerity (which may affect more than 1 in 10 people) are flushing (reddening of the skin) and gastrointestinal problems (such as diarrhoea, nausea, and pain in the abdominal area).

Vumerity 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, see the package leaflet.

Why is Vumerity authorised in the EU?

Vumerity has been shown to be bioequivalent to the authorised medicine Tecfidera (dimethyl fumarate) at recommended doses, producing the same levels of the final active form, monomethyl fumarate, in the body. Therefore, the efficacy and safety profiles of Vumerity are expected to be similar to those of dimethyl fumarate.

Dimethyl fumarate has been shown to be effective in reducing the risk of relapses in patients with relapsing-remitting MS and how often they occur, which is expected to be similar for Vumerity. Like dimethyl fumarate, the main risks with Vumerity are expected to be manageable and include flushing and gastrointestinal problems (the most common side effects), as well as reduced levels of white blood cells and presence of protein in the urine. Additional studies with Vumerity are planned or underway to provide further long-term safety data and to monitor the medicine.

The European Medicines Agency, therefore, decided that Vumerity'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 Vumerity?

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

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

Other information about Vumerity

Vumerity received a marketing authorisation valid throughout the EU on 15 November 2021.

Further information on Vumerity can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/vumerity.

This overview was last updated in 11-2021.