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# Riulvy (*tegomil fumarate*)

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

## What is Riulvy and what is it used for?

Riulvy is a medicine used to treat multiple sclerosis, a disease in which the immune system (the body's natural defences) attacks the protective insulation around nerves (myelin) in the brain and spinal cord, causing inflammation and damage to the nerves themselves. Riulvy is used in adults and children from 13 years of age with a type of multiple sclerosis known as relapsing-remitting, where the patient has flare-ups of symptoms (relapses) followed by periods of recovery (remissions).

Riulvy is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' already authorised in the EU for multiple sclerosis, Tecfidera, but there are differences between the two. The active substances in Riulvy (tegomil fumarate) and Tecfidera (dimethyl fumarate) are different, but they are both quickly broken down in the body into the same active form, monomethyl fumarate. Riulvy is used at higher doses than Tecfidera to achieve the same effects.

## How is Riulvy used?

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

Riulvy is available as capsules to be taken by mouth with food twice a day.

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

## How does Riulvy work?

The active substance in Riulvy, tegomil fumarate, is broken down into the active form monomethyl fumarate in the body. Monomethyl fumarate is thought to work by activating a protein called Nrf2, which help cells produce antioxidants, substances that protect cells from damage. This is expected to reduce inflammation and modulate the activity of the immune system. These effects are thought to protect nerve cells from damage caused by inflammation and to slow down the progression of the disease in people with multiple sclerosis.

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## What benefits of Riulvy have been shown in studies?

The active substances in Riulvy and Tecfidera are quickly broken down in the body into monomethyl fumarate.

Three main studies were carried out in a total of 100 healthy volunteers to show that Riulvy is 'bioequivalent' to the reference medicine, Tecfidera. This means that they produce the same levels of monomethyl fumarate in the body. These studies showed that Riulvy 174 mg and 348 mg capsules are bioequivalent with Tecfidera 120 mg and 240 mg capsules. These doses are therefore expected to have the same effect.

## What are the risks associated with Riulvy?

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

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

Riulvy 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 multiple sclerosis medicines.

## Why is Riulvy authorised in the EU?

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

The active substances in Riulvy and Tecfidera are both quickly broken down into the active form, monomethyl fumarate, before they enter the bloodstream. Their properties therefore do not differ significantly in terms of safety and efficacy. In addition, the authorised doses of Riulvy have been shown to be bioequivalent to those of Tecfidera; they are therefore expected to have the same effect. Based on these data, the benefits and risks of Riulvy are taken as being the same as the reference medicine's.

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

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

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

## Other information about Riulvy

Riulvy received a marketing authorisation valid throughout the EU on 28 July 2025.

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

This overview was last updated in 07-2025.