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# Fingolimod Mylan (*fingolimod*)

An overview of Fingolimod Mylan and why it is authorised in the EU

## What is Fingolimod Mylan and what is it used for?

Fingolimod Mylan is a medicine used to treat adults and children over 10 years of age with highly active relapsing-remitting multiple sclerosis (RRMS). 'Relapsing-remitting' means that the patient has flare-ups of symptoms (relapses) followed by periods with milder or no symptoms (remissions). Fingolimod Mylan is used when the disease remains active despite appropriate treatment with at least one other disease-modifying therapy, or is severe and getting worse rapidly.

Fingolimod Mylan contains the active substance fingolimod and is a 'generic medicine'. This means that Fingolimod Mylan contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Gilenya. For more information on generic medicines, see the question-and-answer document here.

## How is Fingolimod Mylan used?

Fingolimod Mylan can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in multiple sclerosis. Fingolimod Mylan is available as capsules (0.5 mg). The recommended dose for adults is one capsule taken once a day by mouth, the recommended dose for children depends on body weight.

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

## How does Fingolimod Mylan work?

In multiple sclerosis, the immune system (the body's natural defenses) attacks and damages the protective insulation around the nerves and the nerves themselves in the brain and spinal cord. The active substance in Fingolimod Mylan, fingolimod, prevents T cells (a type of white blood cell involved in the immune system) travelling from the lymph nodes towards the brain and spinal cord, thus limiting the damage they cause in multiple sclerosis. It does this by blocking the action of a receptor (target) on the T cells called the sphingosine-1-phosphate receptor, which is involved in controlling the movement of these cells in the body.

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## How has Fingolimod Mylan 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, Gilenya, and do not need to be repeated for Fingolimod Mylan.

As for every medicine, the company provided data on the quality of Fingolimod Mylan. The company also carried out a study 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 Fingolimod Mylan?

Because Fingolimod Mylan 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 Fingolimod Mylan authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Fingolimod Mylan has been shown to have comparable quality and to be bioequivalent to Gilenya. Therefore, the Agency's view was that, as for Gilenya, the benefits of Fingolimod Mylan 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 Fingolimod Mylan?

The company that markets Fingolimod Mylan must ensure that all doctors who prescribe the medicine receive an information pack containing important safety information, including a checklist of the risks with Fingolimod Mylan and the situations where its use is not recommended. The checklist includes information on the tests and monitoring in patients before and during treatment with Fingolimod Mylan. The pack will also include a reminder card for patients or their carers with key safety information about Fingolimod Mylan, and a pregnancy-specific card to remind patients that Fingolimod Mylan must not be used during pregnancy and in women who can become pregnant and are not using effective contraception.

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

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

## Other information about Fingolimod Mylan

Fingolimod Mylan received a marketing authorisation valid throughout the EU on 18 August 2021.

Further information on Fingolimod Mylan can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/fingolimod-mylan. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 08-2021.