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Fingolimod Accord (*fingolimod*)

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

What is Fingolimod Accord and what is it used for?

Fingolimod Accord is a type of medicine known as a 'disease-modifying therapy' that is 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 Accord 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 Accord is a 'generic medicine'. This means that Fingolimod Accord 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.

Fingolimod Accord contains the active substance fingolimod.

How is Fingolimod Accord used?

Fingolimod Accord can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in multiple sclerosis. Fingolimod Accord 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.

Because Fingolimod Accord decreases the heart rate and can affect the heart's electrical activity and rhythm, the patient's blood pressure and heart activity are checked before starting treatment and during treatment, and also if Fingolimod Accord treatment is restarted after an interruption. Details on the recommendations for monitoring patients are found in the summary of product characteristics.

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

How does Fingolimod Accord work?

In multiple sclerosis, the immune system (the body's defences) attacks and damages the protective insulation around the nerves and the nerves themselves in the brain and spinal cord.

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The active substance in Fingolimod Accord, 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.

How has Fingolimod Accord 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 Accord.

As for every medicine, the company provided studies on the quality of Fingolimod Accord. 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 Accord?

Because Fingolimod Accord 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 Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Fingolimod Accord 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 Accord 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 Accord?

The company that markets Fingolimod Accord 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 Accord 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 Accord. The pack will also include a reminder card for patients or their carers with key safety information about Fingolimod Accord, and a pregnancy-specific card to remind patients that Fingolimod Accord 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 Accord have also been included in the summary of product characteristics and the package leaflet.

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

Other information about Fingolimod Accord

Fingolimod Accord received a marketing authorisation valid throughout the EU on 25 June 2020.

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

This overview was last updated in 06-2020.