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Teriflunomide Mylan (*teriflunomide*)

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

What is Teriflunomide Mylan and what is it used for?

Teriflunomide Mylan is a medicine used to treat patients from the age of 10 years with multiple sclerosis (MS), a disease in which inflammation attacks the protective covering (sheath) around nerves and damages the nerves themselves.

Teriflunomide Mylan is used in the type of MS known as relapsing-remitting MS, when the patient has flare-ups of symptoms (relapses) followed by periods of recovery (remissions).

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

Teriflunomide Mylan contains the active substance teriflunomide.

How is Teriflunomide Mylan used?

Teriflunomide Mylan can only be obtained with a prescription and treatment should be started and supervised by a doctor who has experience in the management of MS.

Teriflunomide Mylan is available as tablets. The recommended dose for adults is 14 mg once a day. The dose for children depends on their body weight. For more information about using Teriflunomide Mylan, see the package leaflet or contact your doctor or pharmacist.

How does Teriflunomide Mylan work?

In multiple sclerosis, the immune system (the body's natural defences) incorrectly attacks the protective sheath around the nerves and the nerves themselves in the brain and spinal cord. The active substance in Teriflunomide Mylan, teriflunomide, blocks an enzyme called 'dihydroorotate dehydrogenase' which is necessary for cells to multiply. The exact way teriflunomide works in MS is not known but it is thought to reduce the number of T-lymphocytes which form part of the immune system and are involved in the inflammation process. With fewer T-lymphocytes, there is less inflammation, helping to control the symptoms of MS.

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How has Teriflunomide 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, Aubagio, and do not need to be repeated for Teriflunomide Mylan.

As for every medicine, the company provided studies on the quality of Teriflunomide 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 Teriflunomide Mylan?

Because Teriflunomide 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 Teriflunomide Mylan authorised in the EU?

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

The company that markets Teriflunomide Mylan must ensure that all healthcare professionals who are expected to prescribe this medicine receive educational material containing important safety information, including the tests and monitoring that should be carried out in patients before and after starting treatment. The company must also provide patient education cards with key safety information for patients.

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

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

Other information about Teriflunomide Mylan

Teriflunomide Mylan received a marketing authorisation valid throughout the EU on 9 November 2022.

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

This overview was last updated in 11-2022.