EMA/536291/2024
EMEA/H/C/005962

Teriflunomide Viatris[1] (*teriflunomide*)

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

What is Teriflunomide Viatris and what is it used for?

Teriflunomide Viatris 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 Viatris 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 Viatris contains the active substance teriflunomide and is a 'generic medicine'. This means that Teriflunomide Viatris 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.

How is Teriflunomide Viatris used?

Teriflunomide Viatris 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 Viatris is available as tablets to be taken once a day.

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

How does Teriflunomide Viatris work?

In multiple sclerosis, the immune system (the body's natural defences) attacks the protective sheath around the nerves and the nerves themselves in the brain and spinal cord. The active substance in Teriflunomide Viatris, 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.

[1]Previously known as Teriflunomide Mylan.

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How has Teriflunomide Viatris 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 Viatris.

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

Because Teriflunomide Viatris 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 Viatris authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Teriflunomide Viatris 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 Viatris 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 Viatris?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Teriflunomide Viatris have also been included in the summary of product characteristics and the package leaflet. Any additional measures in place for Aubagio, such as educational material for healthcare professionals and a patient card with key safety information, also apply to Teriflunomide Viatris where appropriate.

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

Other information about Teriflunomide Viatris

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

The name of the medicine was changed to Teriflunomide Viatris on 15 October 2024.

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

This overview was last updated in 12-2024.