EMA/536337/2024
EMEA/H/C/004127

Zonisamide Viatris[1] (*zonisamide*)

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

What is Zonisamide Viatris and what is it used for?

Zonisamide Viatris is a medicine used to treat patients with partial seizures (epileptic fits starting in one part of the brain), including those who have secondary generalisation (where the seizure subsequently spreads to the whole brain). It is used on its own in newly diagnosed adults and as an 'add-on' therapy in adults and children aged six years and above already receiving other anti-epilepsy medicines.

Zonisamide Viatris contains the active substance zonisamide and is a 'generic medicine'. This means that Zonisamide Viatris is similar to a 'reference medicine' already authorised in the EU called Zonegran. For more information on generic medicines, see the question-and-answer document here.

How is Zonisamide Viatris used?

The medicine can only be obtained with a prescription and is available as capsules.

The dose and how often the medicine is taken depends on the condition being treated and whether the patient is an adult or a child.

For further information, see the package leaflet or contact your doctor or pharmacist.

How does Zonisamide Viatris work?

The active substance in Zonisamide Viatris, zonisamide, is an anti-epileptic. Epileptic fits are caused by abnormal electrical activity in the brain.

Zonisamide is thought to work by blocking specific pores on the surface of nerve cells called sodium channels and calcium channels, through which sodium or calcium normally enter nerve cells. When calcium and sodium enter nerve cells, electrical impulses can be transmitted between the nerve cells. By blocking these channels, zonisamide is expected to prevent abnormal electrical activity spreading through the brain, thereby reducing the chances of an epileptic fit.

[1] Previously known as Zonisamide Mylan.

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Zonisamide Viatris also acts on the neurotransmitter gamma-aminobutyric acid (GABA, a chemical that allows nerve cells to communicate with each other). This may help to stabilise electrical activity in the brain.

How has Zonisamide Viatris been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Zonegran, and do not need to be repeated for Zonisamide Viatris.

As for every medicine, the company provided studies on the quality of Zonisamide Viatris. The company also carried out studies 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 Zonisamide Viatris?

Because Zonisamide 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 Zonisamide Viatris authorised for use in the EU?

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Zonisamide Viatris have been included in the summary of product characteristics and the package leaflet. Any additional measures in place for Zonegran also apply to Zonisamide Viatris where appropriate.

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

Other information about Zonisamide Viatris

The European Commission granted a marketing authorisation valid throughout the European Union for Zonisamide Viatris on 31 March 2016.

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

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

This summary was last updated in 12-2024.