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EPAR summary for the public

Zonisamide Mylan

zonisamide

This is a summary of the European public assessment report (EPAR) for Zonisamide Mylan. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Zonisamide Mylan.

For practical information about using Zonisamide Mylan, patients should read the package leaflet or contact their doctor or pharmacist.

What is Zonisamide Mylan and what is it used for?

Zonisamide Mylan 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 Mylan is a 'generic medicine'. This means that Zonisamide Mylan is similar to a 'reference medicine' already authorised in the European Union (EU) called Zonegran.

Zonisamide Mylan contains the active substance zonisamide.

How is Zonisamide Mylan used?

The medicine can only be obtained with a prescription and is available as capsules (25, 50 and 100 mg).

When Zonisamide Mylan is used on its own in newly diagnosed adults, the recommended starting dose is 100 mg once a day for two weeks, which may be increased by 100 mg at intervals of two weeks. The usual maintenance dose is 300 mg a day.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

When Zonisamide Mylan is used as an 'add-on' to existing treatment in adults, the recommended starting dose is 25 mg twice a day. After one or two weeks, the dose may be increased to 50 mg twice a day and then further increased in steps of 100 mg every week or every other week, depending on the patient's response. Zonisamide Mylan can be given once or twice a day after an appropriate dose is reached. The usual maintenance dose is between 300 and 500 mg a day.

When Zonisamide Mylan is used as an 'add-on' to existing treatment in children aged six years and above, the dose depends on body weight; the recommended starting dose is 1 mg per kg of body weight daily. After one or two weeks, the daily dose may be increased in steps of 1 mg per kilogram every one or two weeks until an appropriate dose is reached. The usual maintenance dose is between 300 and 500 mg a day for children weighing more than 55 kg and 6 to 8 mg per kg of body weight in children weighing less than 55 kg.

Dose increases may need to be made less frequently in patients with liver or kidney problems or those taking certain other medicines. Before stopping Zonisamide Mylan, the dose should be decreased gradually. For further information, see the package leaflet.

How does Zonisamide Mylan work?

The active substance in Zonisamide Mylan, 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.

Zonisamide Mylan 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 Mylan been studied?

Because Zonisamide Mylan is a generic medicine, studies in people have been limited to tests to determine that it is bioequivalent to the reference medicine, Zonegran. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Zonisamide Mylan?

Because Zonisamide 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 Zonisamide Mylan approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Zonisamide Mylan has been shown to have comparable quality and to be bioequivalent to Zonegran. Therefore, the CHMP's view was that, as for Zonegran, the benefit outweighs the identified risk. The Committee recommended that Zonisamide Mylan be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Zonisamide Mylan?

A risk management plan has been developed to ensure that Zonisamide Mylan is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Zonisamide Mylan, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Zonisamide Mylan

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

The full EPAR for Zonisamide Mylan can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Zonisamide Mylan, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2016.