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Ontozry (*cenobamate*)

An overview of Ontozry and why it is authorised in the EU

What is Ontozry and what is it used for?

Ontozry is an epilepsy medicine for treating epileptic fits starting in one specific part of the brain (focal seizures), including those that eventually spread to the whole brain (secondary generalisation).

Ontozry is used as an add-on to other epilepsy medicines for adults with seizures that are not controlled despite having tried at least two other treatments.

It contains the active substance cenobamate.

How is Ontozry used?

Ontozry is available as tablets taken once daily. The patient starts with a daily dose of 12.5 mg and the dose increases over several weeks up to a target of 200 mg. If the patient's seizures are still not controlled, the dose may increase to up 400 mg.

The medicine can only be obtained with a prescription. For more information about using Ontozry, see the package leaflet or contact your doctor or pharmacist.

How does Ontozry work?

Epilepsy is caused by abnormal electrical activity in the brain. The exact way in which Ontorzy works is unclear but it affects the activity of channels that allow electrical impulses to be transmitted between nerve cells. This may prevent abnormal electrical activity in the brain, reducing the chance of an epileptic fit.

What benefits of Ontozry have been shown in studies?

In a main study involving 437 patients Ontorzy was more effective than placebo (a dummy treatment) at lowering the number of seizures in patients with uncontrolled partial seizures despite past treatment. Around 40% of patients who took a 100 mg daily dose of Ontorzy during 3 months of treatment and 64% of those who took a 400 mg daily dose had at least a 50% drop in the frequency of their seizures. This compares with 26% of patients taking placebo.

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What are the risks associated with Ontozry?

The most common side effects with Ontozry (which may affect more than 1 in 10 people) are sleepiness, headache and problems with keeping balance.

Ontozry should not be used by patients with familial short QT syndrome, a rare genetic condition that can lead to irregular heart rhythm. For the full list of restrictions and side effects, see the package leaflet.

Why is Ontozry authorised in the EU?

A main study showed that Ontozry can reduce the frequency of seizures in many patients. The side effects that occur most frequently are those that affect the nervous system such as sleepiness, tiredness and dizziness.

The European Medicines Agency concluded that Ontozry's benefits are greater than its risks and that it can be authorised for use in the EU.

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

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

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

Other information about Ontozry

Ontozry received a marketing authorisation valid throughout the EU on 26 March 2021.

Further information on Ontozry can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/ontorzy

This overview was last updated in 03-2021.