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Inovelon (*rufinamide*)

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

What is Inovelon and what is it used for?

Inovelon is an epilepsy medicine used to treat patients aged one year or older who have Lennox-Gastaut syndrome, a rare type of epilepsy that usually affects children but which can continue into adulthood. Lennox-Gastaut syndrome is one of the most severe forms of epilepsy in children. Its symptoms include multiple types of seizure (fits), abnormal electrical activity in the brain, learning disability and behavioural problems. Inovelon is used as an add-on to other anti-epileptic medicines.

Lennox-Gastaut syndrome is rare, and Inovelon was designated an 'orphan medicine' (a medicine used in rare diseases) on 20 October 2004. Further information on the orphan designation can be found here: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

Inovelon contains the active substance rufinamide.

How is Inovelon used?

Inovelon can only be obtained with a prescription and treatment should be started by a paediatrician (a doctor specialised in treating children) or a neurologist (a doctor who treats brain disorders) experienced in the treatment of epilepsy.

The dose of Inovelon depends on the patient's age and weight and whether the patient is also taking valproate (another anti-epileptic medicine). Treatment in children less than 4 years of age generally starts with a daily dose of 10 mg per kilogram body weight. In older patients, treatment usually starts with a dose of 200 or 400 mg daily. The dose is then adjusted every other day according to the patient's response to treatment.

Inovelon should be taken with water and food. The daily dose is divided into two halves, taken morning and evening about 12 hours apart.

The medicine should not be used in patients who have severe problems with their liver. For more information about using Inovelon, see the package leaflet or contact your doctor or pharmacist.

How does Inovelon work?

The active substance in Inovelon, rufinamide, acts by attaching to special channels (sodium channels) on brain cells that control their electrical activity. By attaching to the channels, rufinamide prevents

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them switching from an inactive state to an active state. This dampens down the activity of the brain cells and prevents abnormal electrical activity from spreading through the brain. This reduces the likelihood of a seizure occurring.

What benefits of Inovelon have been shown in studies?

In a main study involving 139 patients aged between 4 and 30 years (three quarters of them below 17 years old) Inovelon caused a reduction in the number and severity of seizures. All of the patients had Lennox-Gastaut syndrome that was not controlled despite continuous treatment for at least four weeks with up to three other anti-epileptic medicines. The study compared the effects of adding Inovelon tablets or adding placebo (a dummy treatment) to the other medicines the patients were taking. The main measures of effectiveness were the change in the number of seizures in the four weeks after Inovelon or placebo was added, compared with the four weeks before it was added, as well as the change in severity of seizures assessed on a 7-point scale by the patient's parent or guardian.

Patients taking Inovelon had a 35.8% reduction in the total number of seizures, falling from an average of 290 seizures in the four-week period before Inovelon was started. There was a 1.6% reduction in the patients who added placebo to their existing treatment.

Patients adding Inovelon also had a 42.5% reduction in the number of 'tonic-atonic' seizures (a common type of fit in patients with Lennox-Gastaut syndrome that often involves the patient dropping to the floor), compared with a 1.9% increase in those adding placebo.

An improvement in the severity of seizures was reported for about half of the patients adding Inovelon, compared with a third of those adding placebo.

A study involving 37 children aged 1 to 4 years was inconclusive because of its small size and because it was not designed to show benefit. However, other analyses showed that doses based on body weight in children aged 1 to 4 years produced similar levels of the medicine in the body to those seen with standard doses in older patients. Given that the disease behaves the same way in both age groups, Inovelon could therefore be expected to act similarly in children aged 1 to 4 years.

The company also presented the results of a study showing that the oral suspension produced the same levels of the active substance in the blood as the tablets.

What are the risks associated with Inovelon?

The most common side effects with Inovelon (seen in more than 1 in 10 patients) are sleepiness, headache, dizziness, vomiting, and tiredness. For the full list of side effects of Inovelon, see the package leaflet.

Inovelon must not be used in patients who are hypersensitive (allergic) to rufinamide, triazole derivatives (such as some medicines used to treat fungal infections) or any of the other ingredients.

Why is Inovelon authorised in the EU?

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

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

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

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

Other information about Inovelon

Inovelon received a marketing authorisation valid throughout the EU on 16 January 2007.

Further information on Inovelon can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

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