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EPAR summary for the public

Inovelon

rufinamide

This is a summary of the European public assessment report (EPAR) for Inovelon. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Inovelon.

What is Inovelon?

Inovelon is a medicine containing the active substance rufinamide. It is available as tablets (100 mg, 200 mg or 400 mg) and as an oral suspension (40 mg/ml).

What is Inovelon used for?

Inovelon is used to treat patients aged four years 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 (fit), abnormal electrical activity in the brain, learning disability and behavioural problems. Inovelon is used as an add-on to other anti-epileptic medicines.

Because the number of patients with Lennox-Gastaut syndrome is low, the disease is rare, and Inovelon was designated an 'orphan medicine' (a medicine used in rare diseases) on 20 October 2004.

The medicine can only be obtained with a prescription.

How is Inovelon used?

Treatment with Inovelon should be started by a paediatrician (a doctor specialised in treating children) or a neurologist (a doctor who treats brain disorders). The doctor should be experienced in the treatment of epilepsy.

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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 generally starts with a daily dose of 200 or 400 mg. This is then adjusted every other day according to the patient's response to treatment.

Inovelon should be taken with water and food twice a day. Half of the total daily dose should be taken in the morning and the other half in the evening. If the patient cannot swallow the tablets, they can be crushed and mixed in a glass of water. Alternatively the oral suspension can be used. Tablets and the oral suspension can be interchanged at the same dose, but patients should be monitored during the switch-over period for any side effects. Inovelon should not be used in patients who have severe problems with their liver. For more information, see the package leaflet.

How does Inovelon work?

The active substance in Inovelon, rufinamide, is an anti-epileptic medicine. It acts by attaching to special channels on the surface of brain cells (sodium channels), which control the electrical activity of the cells. By attaching to the channels, rufinamide prevents 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.

How has Inovelon been studied?

The main study of Inovelon involved 139 patients aged between four and 30 years, of whom three quarters were below 17 years old. 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.

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 benefit has Inovelon shown during the studies?

Inovelon caused a reduction in the number and severity of seizures. 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.

What is the risk associated with Inovelon?

The most common side effects with Inovelon (seen in more than 1 in 10 patients) are somnolence (sleepiness), headache, dizziness, nausea (feeling sick), vomiting, and fatigue (tiredness). For the full list of all side effects reported with 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 has Inovelon been approved?

The CHMP decided that Inovelon's benefits are greater that its risks and recommended that it be given marketing authorisation.

Other information about Inovelon

The European Commission granted a marketing authorisation valid throughout the European Union for Inovelon on 16 January 2007.

The full EPAR for Inovelon 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 Inovelon, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of opinion of the Committee for Orphan Medicinal Products for Inovelon can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designations.

This summary was last updated in 11-2011.