16 December 2016
EMA/848709/2016
EMEA/H/C/II/0037

Questions and answers

Questions and answers on the outcome of an extension of indication application for Inovelon (rufinamide)

The Committee for Medicinal Products for Human Use (CHMP) concluded the review of an application to extend the use of the epilepsy medicine Inovelon to children aged 1 to 4 years. The CHMP considered that the data available at this point in time were not sufficient to recommend this change. However, the Committee considered that the data could be important for healthcare professionals and recommended their inclusion in Inovelon's product information.

What is Inovelon?

Inovelon is used for treating Lennox-Gastaut syndrome, a rare type of epilepsy that usually affects children but can continue into adulthood. It is currently approved only for children aged 4 years or older. Lennox-Gastaut syndrome is one of the most severe forms of epilepsy in children. Its signs and symptoms include multiple types of seizures (fits), abnormal electrical activity in the brain, learning disability and behavioural problems.

Inovelon was designated an 'orphan medicine' (a medicine to be used in rare diseases) on 20 October 2004 for Lennox-Gastaut syndrome. Further information on the orphan designation can be found here.

Inovelon contains the active substance rufinamide and has been authorised since January 2007.

What was Inovelon expected to be used for?

The company that markets Inovelon applied for it to be used to treat Lennox-Gastaut syndrome in children aged 1 to 4 years.

How does Inovelon work?

The active substance in Inovelon, rufinamide acts by attaching to special channels on the surface of brain cells (sodium channels), which control their electrical activity. By attaching to these channels, rufinamide prevents them from becoming activated. This dampens down the activity of the brain cells

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

An agency of the European Union

© European Medicines Agency, 2017. Reproduction is authorised provided the source is acknowledged.

and prevents abnormal electrical activity from spreading through the brain. This reduces the likelihood of a seizure occurring.

What did the company present to support its application?

The company presented data from a study in which 37 children aged between 1 and 4 years with Lennox-Gastaut syndrome received either Inovelon or another epilepsy medicine in addition to their existing treatment. The study investigated the safety of Inovelon and also its impact on the child's behavioural and emotional development assessed by the patient's parent or guardian on a standardised scoring system.

The company also proposed a way to make predictions on the use of Inovelon in children aged between 1 and 4 years based on existing data in patients aged 4 years and older.

What was the conclusion of the CHMP?

While the study showed that the safety of Inovelon in patients aged 1 to less than 4 years was consistent with the known safety profile in older children, the CHMP concluded that the study was too small to make conclusions on the medicine's effectiveness. Regarding the data that the company used to make predictions for use in children aged 1 to less than 4 years, the CHMP considered that further analyses were needed in order to make dosing recommendations in the younger age group. The CHMP therefore concluded that based on the currently available data, Inovelon could not be approved for patients with Lennox-Gastaut syndrome aged less than 4 years.

However, the CHMP considered that including the data obtained in these children in Inovelon's product information could help the healthcare professionals who manage them.

What are the consequences for patients in clinical trials?

There are no consequences of the outcome of this application on patients currently in or who may be joining clinical trials with Inovelon. If you are in a clinical trial and need more information about your treatment, contact the doctor who is giving it to you.

What is happening with Inovelon for the treatment of other diseases?

There are no consequences on the use of Inovelon in patients with Lennox-Gastaut syndrome aged 4 years and over.

More information about Inovelon is available on EMA's website.