EMA/519635/2018
EMEA/H/C/004534

Kigabeq (*vigabatrin*)

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

What is Kigabeq and what is it used for?

Kigabeq is a medicine for treating epilepsy in children between 1 month and 7 years of age. It is used in the following ways:

- on its own to treat infantile spasms (West syndrome), a rare epilepsy disorder that starts at a very young age, usually in the first few months of life;
- together with other medicines to treat partial epilepsy (seizures affecting one part of the brain), including when the seizures spread to other parts of the brain and become more generalised. Kigabeq is only used in partial epilepsy when patients have already tried all other appropriate treatments or cannot use them because of side effects.

Kigabeq contains the active substance vigabatrin and is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' containing the same active substance, but Kigabeq is available in a different form and strengths. The reference medicine for Kigabeq is Sabril (500 mg granules).

How is Kigabeq used?

Kigabeq can only be obtained with a prescription and treatment must started and supervised by a doctor specialising in the treatment of epilepsy or nervous system disorders. The medicine is available as soluble tablets of 100 or 500 mg, with a score-line so they can be halved. The tablets are dissolved in water to make a solution for the patient to drink. In patients who cannot drink it can be given by a tube into the stomach.

The dose depends on the condition being treated and the patient's body weight, and is adjusted according to the patient's response to treatment. For more information about using Kigabeq, see the package leaflet or contact your doctor or pharmacist.

How does Kigabeq work?

The active substance in Kigabeq, vigabatrin, blocks the action of an enzyme called GABA transaminase, which breaks down a substance in the brain called GABA (gamma aminobutyric acid). GABA reduces

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the electrical activity of the brain. Blocking the enzyme that breaks it down increases the amount of GABA present in the brain, and so increases its effect. This helps suppress the abnormal electrical activity that leads to infantile spasms and partial epilepsy, and so controls the symptoms of these conditions.

What benefits of Kigabeq have been shown in studies?

The company provided information from the published literature on the benefits and risks of vigabatrin in the approved uses.

As for every medicine, the company provided studies on the quality of Kigabeq. It also carried out a study that showed that Kigabeq is bioequivalent to the reference medicine, Sabril. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the risks associated with Kigabeq?

The most common side effects with vigabatrin (which may affect more than 1 in 10 people) are visual field defects (effects on vision), tiredness, sleepiness and joint pains. Because the effects on vision can lead to blindness, vigabatrin should only be used after careful assessment of possible alternatives, and patients' vision must be regularly tested during treatment. Vigabatrin should not be used in patients who already have visual field defects.

Other common side effects include psychiatric disorders such as agitation, excitedness, aggression, nervousness, depression and paranoid reactions, as well as reduced consciousness and confusion. Rarely there may be effects on the retina (the light-sensing layer at the back of the eye), encephalopathy (brain damage) or attempts at suicide.

For the full list of side effects and restrictions with Kigabeq, see the package leaflet.

Why is Kigabeq authorised in the EU?

The European Medicines Agency decided that in accordance with EU requirements, Kigabeq has been shown to have comparable quality and to be bioequivalent to Sabril. Therefore, the Agency's view was that, as for Sabril, Kigabeq'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 Kigabeq?

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

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

Other information about Kigabeq

Kigabeq received a marketing authorisation valid throughout the EU on 20 September 2018.

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

This overview was last updated in 09-2018.