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Briviact[1] *(brivaracetam)*

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

What is Briviact and what is it used for?

Briviact is an epilepsy medicine used as an add-on to other epilepsy medicines to treat partial-onset seizures (epileptic fits starting in one specific part of the brain). It can be used in patients from the age of 4 years with partial-onset seizures with or without secondary generalisation (where the abnormal electrical activity spreads through the brain).

Briviact contains the active substance brivaracetam.

How is Briviact used?

Briviact is available as tablets (10, 25, 50, 75 and 100 mg), an oral solution (10 mg/ml) and a solution for injection or infusion (drip) into a vein (10 mg/ml), which is used when the medicine cannot be given by mouth.

The recommended starting dose in adults and younger patients weighing more than 50 kg is either 25 mg twice a day or 50 mg twice a day, depending on the patient's condition. In those weighing less than 50 kg the dose is based on body weight and the usual starting dose is 0.5 mg per kg body weight twice a day. The dose can then be adjusted according to the patient's needs up to a maximum of 100 mg or 2 mg per kg respectively, twice a day.

The medicine can only be obtained with a prescription.

For more information about using Briviact, see the package leaflet or contact a doctor or pharmacist.

How does Briviact work?

Epilepsy is caused by excessive electrical activity in certain areas of the brain. The exact way in which brivaracetam, the active substance in Briviact, works is not clear but it attaches to a protein called synaptic vesicle protein 2A, which is involved in the release of chemical messengers from nerve cells. This helps Briviact to stabilise electrical activity in the brain and prevent seizures.

[1] In Italy: Nubriveo

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What benefits of Briviact have been shown in studies?

Briviact is more effective than placebo (a dummy treatment) at reducing seizures. This was shown in three main studies involving a total of 1,558 patients aged 16 years and above. Either Briviact or placebo was added to patients' usual epilepsy treatment. Taking the studies together, the frequency of seizures was at least halved in 34 to 38% of those adding Briviact at doses from 25 to 100 mg twice a day. This compares with 20% in those adding placebo.

Supportive studies showed that the doses recommended for children produced similar amounts of the medicine in the body to those seen with recommended doses in adults. Therefore Briviact is expected to work in children in the same way.

What are the risks associated with Briviact?

The most common side effects with Briviact (which may affect more than 1 in 10 people) are somnolence (sleepiness) and dizziness. For the full list of side effects of Briviact, see the package leaflet.

Briviact must not be used in patients who are hypersensitive (allergic) to brivaracetam, to other pyrrolidone derivatives (substances that are chemically similar to brivaracetam), or to any of the other ingredients.

Why is Briviact authorised in the EU?

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

Clinical studies have shown add-on treatment with Briviact to be more effective than placebo for controlling partial-onset seizures in adults and children from 4 years of age. Most side effects of Briviact were of mild or moderate severity and were considered manageable.

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

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

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

Other information about Briviact

Briviact received a marketing authorisation valid throughout the EU on 14 January 2016.

Further information on Briviact 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 07-2018.