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EPAR summary for the public

Fycompa

perampanel

This is a summary of the European public assessment report (EPAR) for Fycompa. 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 Fycompa.

What is Fycompa?

Fycompa is a medicine that contains the active substance perampanel. It is available as tablets (2, 4, 6, 8, 10 and 12 mg) and as an oral suspension (0.5 mg/ml, to be taken by mouth).

What is Fycompa used for?

Fycompa is used to treat adults and children from 12 years of age with partial-onset seizures (epileptic fits) with or without secondary generalisation. This is a type of epilepsy where too much electrical activity in one part of the brain causes symptoms such as sudden, jerky movements of one part of the body, distorted hearing, sense of smell or vision, numbness or a sudden sense of fear. Secondary generalisation occurs when the excessive electrical activity subsequently reaches the whole brain.

Fycompa is also used in patients from 12 years of age to treat primary generalised tonic-clonic seizures (major fits or convulsions, where the person becomes unconscious, falls down if standing, and jerks or shakes) associated with idiopathic generalised epilepsy (epilepsy with no apparent cause that is thought to have a genetic origin and that affects the whole brain).

Fycompa must only be used as an ‘add-on’ therapy to other anti-epileptic medicines.

The medicine can only be obtained with a prescription.

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How is Fycompa used?

Fycompa is taken by mouth once a day at bedtime. Fycompa tablets can be taken with or without food and should not be chewed, crushed or split. Fycompa oral suspension can be taken with or without food and should always be taken in the same way (i.e. always with food or always without food).

The recommended dose at the start of treatment is 2 mg per day, and if it is well tolerated the doctor may progressively increase it by increments of 2 mg/day to a maximum dose of 12 mg per day. The dose should not exceed 8 mg per day in patients with mildly or moderately reduced liver function.

How does Fycompa work?

The active substance in Fycompa, perampanel, is an anti-epileptic medicine. Epilepsy is caused by excessive electrical activity in the brain. Although the precise mechanism by which Fycompa works is not fully understood, it is thought to block the action of the neurotransmitter glutamate. Neurotransmitters are naturally-occurring chemicals in the nervous system that allow nerve cells to communicate with each other. Glutamate is the main stimulatory neurotransmitter in nerve cells which can trigger and maintain seizures. Therefore by blocking glutamate's actions, Fycompa is thought to stop epileptic seizures from occurring.

How has Fycompa been studied?

In the management of partial onset seizures, Fycompa has been compared with placebo (a dummy treatment) in three main studies involving a total of 1,491 patients aged 12 years and older with partial-onset seizures who did not respond to other treatments. In these studies, Fycompa was given at a dose of 2, 4, 8 or 12 mg per day for up to 19 weeks. All patients were also taking other anti-epileptic medicines. The main measure of effectiveness was the percentage of patients who experienced at least a 50% decrease in seizure frequency.

For primary generalised tonic-clonic seizures Fycompa was shown to be effective in a study involving 164 patients with idiopathic generalised epilepsy. Fycompa was compared with placebo as an addition to patients' existing epilepsy treatment. Treatment was started at a dose of 2 mg of Fycompa and gradually increased over 4 weeks to a maximum of 8 mg if tolerated, then continued for a further 13 weeks. The main measure of effectiveness was the percentage of patients who experienced at least a 50% decrease in seizure frequency.

What benefit has Fycompa shown during the studies?

Fycompa at doses from 4 mg to 12 mg was shown to be more effective than placebo in reducing the frequency of epileptic seizures. In the first study, the percentage of patients who experienced a decrease in seizure frequency of at least 50% was 37.6% for patients taking 8 mg Fycompa and 36.1% for patients taking 12 mg Fycompa, compared with 26.4% of patients taking placebo. In the second study, 33.3% and 33.9% of patients taking 8 mg and 12 mg Fycompa respectively showed a decrease in seizure frequency of at least 50%, compared with 14.7% of patients taking placebo. The third study showed a significant decrease in seizure frequency only in patients taking 4 mg and 8 mg Fycompa but not in patients taking a dose of 2 mg.

For patients with primary generalised tonic-clonic seizures Fycompa was also more effective than placebo: 47 of 81 patients (58%) given Fycompa had at least a 50% reduction in frequency of seizures, compared with 29 of 81 (36%) of those given the dummy treatment. Supportive evidence

from patients treated for up to 2 years suggested that the benefit was maintained with longer treatment and that some patients could benefit from doses up to 12 mg.

What is the risk associated with Fycompa?

The most common side effects with Fycompa (seen in more than 1 patient in 10) are dizziness and somnolence (sleepiness). For the full list of all side effects and restrictions with Fycompa, see the package leaflet.

Why has Fycompa been approved?

The CHMP considered that Fycompa, taken together with other anti-epileptic medicines, showed a consistent reduction in the frequency of epileptic fits and that no serious toxicity has been identified. Therefore, the CHMP decided that Fycompa's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

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

Other information about Fycompa

The European Commission granted a marketing authorisation valid throughout the European Union for Fycompa on 23 July 2012.

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

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