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Fycompa (perampanel)

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

What is Fycompa and what is it used for?

Fycompa is an epilepsy medicine for treating:

- partial seizures (fits starting in one specific part of the brain), including those followed by generalised seizures affecting all of the brain, in patients from 4 years of age;
- primary generalised tonic-clonic seizures (major fits fit affecting most or all of the brain) in patients from 7 years of age when the cause of epilepsy is unknown.

Fycompa must only be used as an 'add-on' therapy to other anti-epileptic medicines. It contains the active substance perampanel.

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).

For patients above 12 years of age, 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. For younger patients the dose depends on their weight.

Fycompa can only be obtained with a prescription. For more information about using Fycompa, see the package leaflet or contact your doctor or pharmacist.

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 that can trigger and maintain seizures. Therefore, by blocking glutamate's actions, Fycompa is thought to stop epileptic seizures from occurring.

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What benefits of Fycompa have been shown in studies?

Three main studies involving a total of 1,491 patients aged 12 years and older showed that Fycompa was more effective than placebo (a dummy treatment) in reducing the frequency of partial 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.

A fourth study in 164 patients with generalised epilepsy of unknown cause also showed that Fycompa was 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.

Additional data indicate that Fycompa is as effective in younger children as in those above 12 years of age.

What are the risks 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 is Fycompa authorised in the EU?

Studies showed that Fycompa, taken together with other anti-epileptic medicines, showed a consistent reduction in the frequency of epileptic fits and its side effects are manageable. The European Medicines Agency decided that Fycompa'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 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.

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

Other information about Fycompa

Fycompa received a marketing authorisation valid throughout the EU on 23 July 2012.

Further information on Fycompa can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/fycompa

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