European Medicines Agency

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# EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

## EXALIEF

## EPAR summary for the public

*This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.*
*If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).*



**What is Exalief?**
Exalief is a medicine that contains the active substance eslicarbazepine acetate. It is available as white tablets (round: 400 mg; oblong: 600 mg and 800 mg).

**What is Exalief used for?**
Exalief is used to treat adults with partial-onset seizures (epileptic fits) with or without secondary generalisation. This is a type of epilepsy where too much electrical activity in one side 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 overactivity later reaches the whole brain. Exalief must only be used as an 'add-on' to other anti-epileptic medicines.
The medicine can only be obtained with a prescription.

**How is Exalief used?**
Exalief treatment starts at a dose of 400 mg once a day, before increasing it to the standard dose of 800 mg once a day after one or two weeks. The dose may be increased to 1,200 mg once a day depending on how the patient responds to treatment. Exalief can be taken with or without food. Exalief should be used with caution in patients aged above 65 years because there is not enough information on the medicine's safety in these patients. Exalief should also be used with caution in patients with kidney problems and the dose should be adjusted according to how the kidneys are functioning. The medicine is not recommended in patients with severe problems with their kidneys or liver. Exalief is also not recommended in children below 18 years of age.

**How does Exalief work?**
The active substance in Exalief, eslicarbazepine acetate, is converted into the anti-epileptic medicine eslicarbazepine in the body. Epilepsy is caused by excessive electrical activity in the brain. For electrical impulses to travel along nerves there needs to be a rapid movement of sodium into the nerve cells. Eslicarbazepine is thought to work by blocking 'voltage-gated sodium channels', which stops sodium entering the nerve cells. This reduces the activity of the nerve cells in the brain, reducing the intensity and the number of seizures.

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**How has Exalief been studied?**
The effects of Exalief were first tested in experimental models before being studied in humans. Three main studies were performed, involving a total of 1,050 adults with partial-onset seizures that were not controlled by other medicines. All three studies compared Exalief given at different doses (400 mg, 800 mg or 1200 mg once a day) with placebo (a dummy treatment). All of the patients also received other anti-epileptic medicines. The main measure of effectiveness for the three studies was the reduction in the number of seizures over 12 weeks.

**What benefit has Exalief shown during the studies?**
Looking at the results of the three studies taken together, Exalief 800 mg and 1200 mg were more effective than placebo at reducing the number of seizures, when used as add-ons to other anti-epileptic medicines. At the start of the study, patients had around 13 seizures per month. Over the 12 weeks of treatment, this fell to 9.8 and 9 seizures per month in patients taking Exalief 800 mg and Exalief 1200 mg respectively, compared with 11.7 per month in those taking placebo.

**What is the risk associated with Exalief?**
Almost a half of the patients treated with Exalief experience side effects. The most common side effects with Exalief (seen in more than 1 patient in 10) are dizziness and somnolence (sleepiness). For the full list of all side effects reported with Exalief, see the Package Leaflet.
Exalief should not be used in people who may be hypersensitive (allergic) to eslicarbazepine acetate, any of the other ingredients or other carboxamide derivatives (medicines with a similar structure to eslicarbazepine acetate, such as carbamazepine or oxcarbazepine). It must not be used in people with second or third degree atrioventricular block (a problem with electrical transmission in the heart).

**Why has Exalief been approved?**
The Committee for Medicinal Products for Human Use (CHMP) decided that Exalief's benefits are greater than its risks for the treatment of partial-onset seizures with or without secondary generalisation in adults who are also taking other anti-epilepsy medicines. The Committee recommended that Exalief be given marketing authorisation.

**Other information about Exalief:**
The European Commission granted a marketing authorisation valid throughout the European Union for Exalief to Bial - Portela & Ca, SA on 21 April 2009.

The full EPAR for Exalief can be found here.

**This summary was last updated in 02-2009.**