

Carbamazepine for managing aggression and agitation in people with dementia

Information for the public

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About this information

This information explains the evidence summary about the off-label use of carbamazepine for managing aggression and agitation in people with dementia. The evidence summary is an overview of the available information about this medicine. It aims to help prescribers and patients when they are considering whether or not to use an unlicensed or off-label treatment. The summary does not contain recommendations from NICE on whether the medicine should be used.

Using valproate preparations for managing aggression and agitation in people with dementia is covered in another [evidence summary](#).

Licensing medicines

In the UK, medicines need to have a licence before they can be marketed. To get a licence, the manufacturer of the medicine has to provide evidence that shows that the medicine works well enough and is safe enough to be used for a specific condition and for a specific group of patients, and that it can manufacture the medicine to the required quality. Medicines can be prescribed without a licence (an 'unlicensed medicine') if there is no suitable licensed alternative and it is likely to benefit the patient.

A medicine can also be prescribed 'off label'. This means the prescriber wants to use it in a different way than is set out in the terms of its licence. This could mean using the medicine for a different

condition or a different group of patients, or it could mean a change in the dose or that the medicine is taken in a different way. There is more information about licensing medicines on [NHS Choices](#).

What is dementia?

Dementia is a disorder that affects how the brain works. Symptoms of dementia vary from person to person, but can include:

- loss of memory
- difficulty thinking things through and understanding
- problems with language (reading and writing)
- confusion
- agitation and aggression
- depression and anxiety
- hallucinations (seeing or hearing things that are not really there) and delusions (believing things that are not real).

Severe symptoms may make it difficult for the person to do usual daily activities or to care for him or herself.

Dementia usually gets worse over time, but treatment can slow this down and may help with some of the symptoms. There are 2 kinds of treatment:

- treatments that may help with symptoms that affect thinking and memory (cognitive symptoms)
- treatments that may help with symptoms that affect mood and behaviour (non-cognitive symptoms).

People with dementia who have symptoms that affect behaviour should only be offered medication for this if they are very distressed or are at risk of hurting themselves or someone else. People who have psychosis (hallucinations or delusions) or severe agitation may be offered a type of medicine called an [antipsychotic](#) for the short-term treatment of symptoms. Other medicines may be used occasionally if the antipsychotic doesn't work or causes side effects.

More information about dementia and managing dementia is available in the NICE guideline on [supporting people with dementia and their carers](#).

About carbamazepine

Carbamazepine is used to prevent fits in some forms of epilepsy. It is also used to treat a painful condition of the face called trigeminal neuralgia and to help control serious mood disorders when some other medicines don't work. It is taken by mouth as a tablet or liquid.

Carbamazepine is sometimes used to manage aggression and agitation in people with dementia, but this use is off-label.

Summary of possible benefits and harms

How well does carbamazepine work?

Four small, short-term studies have looked at how well carbamazepine manages aggression and agitation in people with dementia. All the studies used aggression or behaviour rating scales to find out whether symptoms improved with carbamazepine. The results did not all agree. Overall, 2 studies showed that carbamazepine improved symptoms more than placebo (dummy tablets), but 2 others didn't.

One study included 19 women with dementia who were also wandering, restless or physically aggressive. It found that taking carbamazepine for 4 weeks did not improve behaviour rating scores compared with placebo (dummy tablets).

A second study included 6 people with severe Alzheimer's disease (a type of dementia) who were aggressive. In this study, taking carbamazepine for 8 weeks reduced aggression more than taking placebo.

Another study included 21 people with severe Alzheimer's disease who had been very agitated for over 1 month and whose symptoms had not improved with antipsychotic medicines. The study found that, over 6 weeks, there was no difference in overall behaviour rating scores between people taking carbamazepine and those taking placebo. However, people taking carbamazepine showed less hostility than those taking placebo.

The largest study included 51 people with severe Alzheimer's disease or other type of dementia, who had been agitated for at least 2 weeks. In this study carbamazepine was better than placebo

for improving overall behaviour scores after 6 weeks, mainly because of improvements in agitation and hostility. Carbamazepine also improved other measures of aggression and behaviour more than placebo.

All the studies were short and no information is available on how well carbamazepine works in the long term for managing aggression and agitation in people with dementia. Also, all studies compared carbamazepine with placebo so it is not known how carbamazepine compares with other medicines used for dementia. The average age of people in the studies was 79 years, and most were women with severe dementia. Therefore, it isn't clear how well carbamazepine works in younger people, men or people with less severe dementia.

What are the possible harms or side effects?

In 3 studies, carbamazepine treatment was tolerated well (with few side effects) but in 1 study people had more problems with side effects. In the largest study, side effects were more common with carbamazepine (occurring in 16 out of 27 people) than with placebo (7 out of 24 people). In the second largest study, side effects occurred in 4 out of 9 people taking carbamazepine and 8 out of 12 people taking placebo.

The following common side-effects (occurring in 1 in 100 people or more) may occur when taking carbamazepine, particularly at first, although some of these usually settle down over time:

- dizziness and problems with balance and coordination
- tiredness and feeling sleepy
- headache
- blurred or double vision
- feeling sick and being sick
- water retention
- allergic skin reactions.

Carbamazepine sometimes causes blood disorders called leukopenia, thrombocytopenia and eosinophilia. Doctors can advise what signs to look out for.

Please note that the results of the research studies only indicate the benefits and harms for the population in the studies. It is not possible to predict what the benefits and harms will be for an individual patient being treated with carbamazepine.

Prescribing carbamazepine

If a prescriber wants to use an unlicensed or off-label medicine, they must follow their professional guide, for example for doctors the General Medical Council's [good practice guidelines](#). These include giving information about the treatment and discussing the possible benefits and harms so that the person has enough information to decide whether or not to have the treatment. This is called giving informed consent.

A [full version of the summary aimed at healthcare professionals](#) is available on the NICE website. The summary for healthcare professionals does not contain recommendations from NICE on whether the medicine should be used.

Questions to ask

- Why am I, or someone I care for, being offered an off-label medicine?
- What does the treatment involve?
- What are the possible benefits?
- How good are the chances of getting those benefits?
- Could having the treatment make me, or the person I care for, feel worse?
- Are there alternative treatments?
- What are the risks of the treatment?
- Are the risks minor or serious? How likely are they to happen?
- What may happen if I or the person I care for doesn't have the treatment?

More information

NICE has published [information](#) about how evidence summaries for unlicensed and off-label medicines are developed.

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