Patient Decision Aid
Oxcarbazepine add-on therapy for drug-resistant focal epilepsy
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This summary is to help you talk with your doctor about using oxcarbazepine (Trileptal) in addition to your current epilepsy medicine. It explains the evidence about the main benefits and risks of taking oxcarbazepine alongside other epilepsy medicines. If your doctor recommends taking oxcarbazepine, it is your decision whether to take it or not.

Who and what is oxcarbazepine for?

Oxcarbazepine is for people who have epilepsy, who are still having seizures, despite taking one or more epilepsy medicines. Oxcarbazepine can be used as an add-on therapy, meaning that you take it alongside your other epilepsy medicines. The aim is to reduce or stop your seizures. Doctors can prescribe oxcarbazepine to treat focal-onset seizures (which start in one side of the brain) with or without secondary generalisation (when a seizure spreads to affect both sides of the brain) that are not controlled by other epilepsy medicines.

Where did we get this information?

We looked at results from six clinical trials. In total, the trials included 1593 people. All of these people had drug-resistant focal epilepsy and were between 1 month and 65 years old. This Patient Decision aid is, therefore, for children and adults with drug-resistant focal epilepsy.

In these trials, people took either oxcarbazepine or a fake, inactive medicine (placebo). Both groups continued to take their usual epilepsy medicine as well.

The information in this resource is current to September 2018.
What are the main benefits of using oxcarbazepine?

It is not possible to know in advance what will happen for any individual person. But from the trial results, we found:

**Reduction in seizures**

For every 100 people with drug-resistant focal epilepsy who took oxcarbazepine with their usual epilepsy medicine, 39 had a 50% or greater reduction in seizures, and 61 did not.

In comparison, for every 100 people with drug-resistant focal epilepsy who took a placebo with their usual epilepsy medicine, 22 had a 50% or greater reduction in seizures and 78 did not.

These numbers show that people taking oxcarbazepine were twice as likely to have a 50% reduction in seizures as people taking a placebo.

**How confident are we that these findings are correct?**

We grade the evidence we look at. We use these grades to decide how confident we are that our findings are accurate.

We graded the evidence for 50% or greater reduction in seizures to be of low certainty. This means we are not certain that these findings are accurate.
Seizure freedom

For every 100 people with drug-resistant focal epilepsy who took oxcarbazepine with their usual epilepsy medicine, 10 became seizure-free, and 90 did not.

In comparison, for every 100 people with drug-resistant focal epilepsy who took a placebo with their usual epilepsy medicine, 4 became seizure-free and 96 did not.

These numbers show that people taking oxcarbazepine were three times as likely to become seizure free, as people taking a placebo.

How confident are we that these findings are correct?

We graded the evidence for seizure freedom to be of low certainty. This means we are not certain that these findings are accurate.
What are the main risks of taking oxcarbazepine?
Like any medicine, oxcarbazepine carries a risk of side-effects (see page 5 for possible side-effects). This is what we found from the evidence.

**Withdrawing from the trials**

For every 100 people with drug-resistant epilepsy who took **oxcarbazepine** with their usual epilepsy medicine, 29 withdrew from the trials, and 71 did not.

For every 100 people with drug-resistant epilepsy who took a **placebo** with their usual epilepsy medicine, 17 withdrew from the trials, and 83 did not.

These numbers show that people taking **oxcarbazepine** were twice as likely to withdraw from trials as people taking a **placebo**.

We did not study the reasons why people withdrew from trials. Possible reasons might include that they experienced side-effects, because the medicine did not improve their seizures, due to personal reasons, such as moving home, or other reasons.

**How confident are we that these findings are correct?**

We graded the evidence for withdrawal from treatment to be of moderate certainty. This means we are fairly confident that these findings are accurate.
What are the main side-effects of oxcarbazepine?

It is not possible to know in advance what will happen to any individual person when they take medicine. We investigated side-effects that we know commonly affect people taking epilepsy medicine.

**Ataxia (problems with balance, co-ordination and speech)**

For every 100 people with drug-resistant focal epilepsy who took oxcarbazepine with their usual epilepsy medicine, 13 experienced ataxia and 87 did not.

For every 100 people with drug-resistant focal epilepsy who took a placebo with their usual epilepsy medicine, 5 experienced ataxia and 95 did not.

**Dizziness**

For every 100 people with drug-resistant focal epilepsy who took oxcarbazepine with their usual epilepsy medicine, 31 experienced dizziness, and 69 did not.

For every 100 people with drug-resistant focal epilepsy who took a placebo with their usual epilepsy medicine, 12 experienced dizziness, and 88 did not.
Fatigue (feeling very tired in body and mind)
For every 100 people with drug-resistant focal epilepsy who took oxcarbazepine with their usual epilepsy medicine, 11 experienced fatigue, and 89 did not.

For every 100 people with drug-resistant focal epilepsy who took a placebo with their usual epilepsy medicine, 6 experienced fatigue, and 94 did not.

Headache
For every 100 people with drug-resistant focal epilepsy who took oxcarbazepine with their usual epilepsy medicine, 23 experienced headache, and 77 did not.

For every 100 people with drug-resistant focal epilepsy who took a placebo with their usual epilepsy medicine, 18 experienced headache, and 82 did not.

Nausea (feeling sick)
For every 100 people with drug-resistant focal epilepsy who took oxcarbazepine with their usual epilepsy medicine, 15 experienced nausea, and 85 did not.

For every 100 people with drug-resistant focal epilepsy who took a placebo with their usual epilepsy medicine, 8 experienced nausea, and 92 did not.
Drowsiness (feeling sleepy)

For every 100 people with drug-resistant focal epilepsy who took oxcarbazepine with their usual epilepsy medicine, 24 experienced drowsiness, and 76 did not.

For every 100 people with drug-resistant focal epilepsy who took a placebo with their usual epilepsy medicine, 12 experienced drowsiness, and 88 did not.

Infection

For every 100 people with drug-resistant epilepsy who took oxcarbazepine with their usual epilepsy medicine, 19 reported infection, and 81 did not.

For every 100 people with drug-resistant epilepsy who took a placebo with their usual epilepsy medicine, 9 reported infection, and 91 did not.

Vertigo (the sensation that you or everything around you is spinning)

For every 100 people with drug-resistant focal epilepsy who took oxcarbazepine with their usual epilepsy medicine, 8 experienced vertigo, and 92 did not.

For every 100 people with drug-resistant focal epilepsy who took a placebo with their usual epilepsy medicine, 2 experienced vertigo, and 98 did not.
**Diplopia (double vision)**

For every 100 people with drug-resistant focal epilepsy who took **oxcarbazepine** with their usual epilepsy medicine, 17 experienced double vision, and 83 did not.

For every 100 people with drug-resistant focal epilepsy who took a **placebo** with their usual epilepsy medicine, 3 experienced double vision, and 97 did not.

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**Rash**

For every 100 people with drug-resistant focal epilepsy who took **oxcarbazepine** with their usual epilepsy medicine, 5 reported a rash, and 95 did not.

For every 100 people with drug-resistant focal epilepsy who took a **placebo** with their usual epilepsy medicine, 4 reported a rash, and 96 did not.

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**Tremor**

For every 100 people with drug-resistant focal epilepsy who took **oxcarbazepine** with their usual epilepsy medicine, 9 experienced tremor, and 91 did not.

For every 100 people with drug-resistant focal epilepsy who took a **placebo** with their usual epilepsy medicine, 4 experienced tremor, and 96 did not.
Fever

For every 100 people with drug-resistant focal epilepsy who took **oxcarbazepine** with their usual epilepsy medicine, 13 experienced fever, and 87 did not.

For every 100 people with drug-resistant focal epilepsy who took a **placebo** with their usual epilepsy medicine, 10 experienced fever, and 90 did not.

Stomach pain

For every 100 people with drug-resistant epilepsy who took **oxcarbazepine** with their usual epilepsy medicine, 10 experienced stomach pain, and 90 did not.

For every 100 people with drug-resistant epilepsy who took a **placebo** with their usual epilepsy medicine, 7 experienced stomach pain, and 93 did not.

Nystagmus (uncontrollable, repetitive eye movements)

For every 100 people with drug-resistant focal epilepsy who took **oxcarbazepine** with their usual epilepsy medicine, 14 experienced nystagmus, and 86 did not.

For every 100 people with drug-resistant focal epilepsy who took a **placebo** with their usual epilepsy medicine, 3 experienced nystagmus, and 97 did not.
**Vomiting**

For every 100 people with drug-resistant focal epilepsy who took **oxcarbazepine** with their usual epilepsy medicine, 19 experienced vomiting, and 81 did not.

For every 100 people with drug-resistant focal epilepsy who took a **placebo** with their usual epilepsy medicine, 8 experienced vomiting, and 92 did not.

**Abnormal vision**

For every 100 people with drug-resistant focal epilepsy who took **oxcarbazepine** with their usual epilepsy medicine, 11 reported change to their vision, and 89 did not.

For every 100 people with drug-resistant focal epilepsy who took a **placebo** with their usual epilepsy medicine, 4 reported change to their vision, and 96 did not.

**Upper respiratory infection (such as the common cold and sinus infection)**

For every 100 people with drug-resistant focal epilepsy who took **oxcarbazepine** with their usual epilepsy medicine, 8 reported an upper respiratory tract infection, and 92 did not.

For every 100 people with drug-resistant focal epilepsy who took a **placebo** with their usual epilepsy medicine, 11 reported an upper respiratory tract infection, and 89 did not.
Abnormal gait (a change to the way that a person normally walks)

For every 100 people with drug-resistant focal epilepsy who took **oxcarbazepine** with their usual epilepsy medicine, 11 experienced abnormal gait and 89 did not.

For every 100 people with drug-resistant focal epilepsy who took **placebo** with their usual epilepsy medicine, 2 experienced abnormal gait and 98 did not.

These numbers show that people taking **oxcarbazepine** were more likely to experience: dizziness, fatigue, drowsiness, vertigo, double vision, abnormal gait (a change to how people normally walk), nystagmus (uncontrollable, repetitive eye movements), and vomiting than people taking a **placebo**.

The most common side-effects experienced by people taking **oxcarbazepine** with their usual epilepsy medicine were dizziness and drowsiness.

**Is there any more information about side effects available?**

There is more information about the possible side-effects associated with taking **oxcarbazepine** on the next page.

We have taken this information from the **Summary of Product Characteristics** for **oxcarbazepine**. This was produced by Novartis, the manufacturer of Trileptal, and was approved by either the UK Medicines and Healthcare products Regulatory Agency (MHRA) or the European Medicines Agency (EMA).

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* Source: Trileptal Summary of Product Characteristics. Available at: [https://www.medicines.org.uk/emc/product/3815/smpc#UNDESIRABLE_EFFECTS](https://www.medicines.org.uk/emc/product/3815/smpc#UNDESIRABLE_EFFECTS) [Accessed on 23 July 2020]
Very common side-effects
For every 100 people taking **oxcarbazepine**, more than 10 people will experience these side-effects:

- drowsiness
- headache
- dizziness
- double vision
- feeling sick (nausea) and being sick (vomiting)
- fatigue (feeling very tired in body and mind)

Common side-effects
For every 100 people taking **oxcarbazepine**, between 1 and 10 people will experience these side-effects:

- weight gain
- hyponatraemia (low concentration of sodium in your blood)
- feeling agitated
- large and rapid mood swings that might seem inappropriate for the situation
- feeling confused
- depression
- a lack of feeling and interest
- ataxia (problems with balance, co-ordination and speech)
- tremor
- nystagmus (uncontrollable, repetitive eye movements)
- feeling unable to concentrate
- memory loss
- blurred vision and other changes to vision
- vertigo (the sensation that you or everything around you is spinning)
- diarrhoea
- stomach pain
- constipation
- rash
- patches of hair loss (alopecia)
- acne

There are also other less common side-effects. Your doctor can explain these further.
Women of child-bearing age and women planning pregnancy

Women of child-bearing potential and those planning pregnancy should discuss the effects of both epilepsy, and its treatment, on pregnancy. For women of child-bearing age who wish to take oxcarbazepine, your doctor may wish to discuss family planning and contraception with you.

More information regarding this is available at:
www.epilepsy.org.uk/info/women

Where can I get further information?

Information about epilepsy, including seizure types and treatment, is available from Epilepsy Action at:
www.epilepsy.org.uk/info

The information in this leaflet is also available as a plain language summary from the following webpage (this link also provides information about the review authors, the review funders and any relevant declarations of interest):
www.cochrane.org/CD001908/EPILEPSY_oxcarbazepine-add-therapy-drug-resistant-focal-epilepsy