Patient Decision Aid
Lamotrigine add-on therapy for drug-resistant focal epilepsy

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This summary is to help you talk with your doctor about using lamotrigine (Lamictal) in addition to your current epilepsy medicine. It explains the evidence about the main benefits and risks of taking lamotrigine alongside other epilepsy medicines. If your doctor recommends taking lamotrigine, it is your decision whether to take it or not.

Who and what is lamotrigine for?

Lamotrigine is for people who have epilepsy, who are still having seizures, despite taking one or more epilepsy medicines. Lamotrigine 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 lamotrigine 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 14 clinical trials. In total, the trials included 1806 people. All of these people had drug-resistant focal epilepsy and were between 1 month and 67 years old. This Patient Decision aid is, therefore, for children and adults with drug-resistant focal epilepsy.

In these trials, people took either lamotrigine 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 March 2020.
What are the main benefits of using lamotrigine?

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 lamotrigine with their usual epilepsy medicine, 28 had a 50% or greater reduction in seizures, and 72 did not.

In comparison, for every 100 people with drug-resistant focal epilepsy who took a placebo with their usual epilepsy medicine, 16 had a 50% or greater reduction in seizures and 84 did not.

These numbers show that people taking lamotrigine were almost 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 moderate certainty. This means we are fairly confident that these findings are accurate.
What are the main risks of taking lamotrigine?

Like any medicine, lamotrigine carries a risk of side-effects (see page 4 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 lamotrigine with their usual epilepsy medicine, 18 withdrew from the trials, and 82 did not.

For every 100 people with drug-resistant epilepsy who took a placebo with their usual epilepsy medicine, 16 withdrew from the trials, and 84 did not.

These numbers show that people taking lamotrigine were only slightly more likely to withdraw from the trials than people taking a placebo.

We did not study the reasons why people withdrew from trials. Possible reasons might include because they experienced side-effects, because the medicine did not improve their seizures, because of 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 lamotrigine?

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 lamotrigine with their usual epilepsy medicine, 15 experienced ataxia and 85 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 lamotrigine with their usual epilepsy medicine, 26 experienced dizziness, and 74 did not.

For every 100 people with drug-focal epilepsy who took a placebo with their usual epilepsy medicine, 13 experienced dizziness, and 87 did not.
Double vision
For every 100 people with drug-resistant focal epilepsy who took lamotrigine with their usual epilepsy medicine, 23 experienced double vision, and 77 did not.
For every 100 people with drug-resistant focal epilepsy who took a placebo with their usual epilepsy medicine, 6 experienced double vision, and 94 did not.

Drowsiness
For every 100 people with drug-resistant focal epilepsy who took lamotrigine with their usual epilepsy medicine, 13 experienced drowsiness, and 87 did not.
For every 100 people with drug-resistant focal epilepsy who took a placebo with their usual epilepsy medicine, 10 experienced drowsiness, and 90 did not.

Fatigue (feeling very tired in body and mind)
For every 100 people with drug-resistant focal epilepsy who took lamotrigine with their usual epilepsy medicine, 9 experienced fatigue, and 91 did not.
For every 100 people with drug-resistant focal epilepsy who took a placebo with their usual epilepsy medicine, 11 experienced fatigue, and 89 did not.
Headache

For every 100 people with drug-resistant focal epilepsy who took lamotrigine with their usual epilepsy medicine, 25 experienced headache, and 75 did not.

For every 100 people with drug-resistant focal epilepsy who took a placebo with their usual epilepsy medicine, 22 experienced headache, and 78 did not.

Nausea (feeling sick)

For every 100 people with drug-resistant focal epilepsy who took lamotrigine 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.

These numbers show that people taking lamotrigine were more likely to experience: ataxia (problems with balance, co-ordination and speech), dizziness, nausea, and double vision than people taking a placebo.

The most common side-effects experienced by people taking lamotrigine with their usual epilepsy medicine were dizziness, headache and double vision.
Is there any more information about side effects available?

Here is more information about the possible side-effects associated with taking lamotrigine.

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

**Very common side-effects**

For every 100 people taking lamotrigine, more than 10 people will experience these side-effects:

- headache
- rash

**Common side-effects**

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

- aggression
- diarrhoea
- drowsiness and feeling tired
- dry mouth
- feeling agitated and irritated
- feeling sick (nausea) and being sick (vomiting)
- insomnia (difficulty sleeping)
- pain including back pain and joint pain
- tremor

There are also other less common side-effects. Your doctor can explain these further.

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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 lamotrigine, 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):