Patient Decision Aid
Lamotrigine add-on therapy for drug-resistant generalised tonic-clonic seizures

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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 generalised tonic-clonic seizures (which affect the entire brain from the start of the seizure and cause people to lose consciousness and jerk quickly and rhythmically) that are not controlled by other epilepsy medicines.

Where did we get this information?

We looked at results from three clinical trials. In total, the trials included 300 people. All of these people had drug-resistant generalised tonic-clonic seizures and were aged between 2 years and 74 years. This Patient Decision aid is, therefore, for children and adults with drug-resistant generalised tonic-clonic seizures.

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 2019.
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 generalised tonic-clonic seizures who took lamotrigine with their usual epilepsy medicine, 64 had a 50% or greater reduction in seizures, and 36 did not.

In comparison, for every 100 people with drug-resistant generalised tonic-clonic seizures who took a placebo with their usual epilepsy medicine, 34 had a 50% or greater reduction in seizures and 66 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 low certainty. This means we are not confident that these findings are accurate.
Seizure freedom

For every 100 people with drug-resistant generalised tonic-clonic seizures who took lamotrigine with their usual epilepsy medicine, 19 became seizure-free, and 81 did not.

In comparison, for every 100 people with drug-resistant generalised tonic-clonic seizures who took a placebo with their usual epilepsy medicine, 13 became seizure-free and 87 did not.

These numbers show that people taking lamotrigine were 50% more likely to become seizure free than people taking a placebo.

How confident are we that these findings are correct?

We graded the evidence for seizure freedom to be of very low certainty. This means we are very uncertain 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, 19 withdrew from the trials, and 81 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 are 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 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 very low certainty. This means we are very uncertain 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 all the people with drug-resistant generalised tonic-clonic seizures who took lamotrigine with their usual epilepsy medicine during the trials, 1 experienced ataxia and 134 did not.

For all the people with drug-resistant generalised tonic-clonic seizures who took a placebo with their usual epilepsy medicine during the trials, 0 experienced ataxia and 136 did not.

**Convulsion**

For every 100 people with drug-resistant generalised tonic-clonic seizures who took lamotrigine with their usual epilepsy medicine, 4 experienced convulsion, and 96 did not.

For every 100 people with drug-generalised tonic-clonic seizures who took a placebo with their usual epilepsy medicine, 5 experienced convulsion, and 95 did not.

**Dizziness**

For every 100 people with drug-resistant generalised tonic-clonic seizures who took lamotrigine with their usual epilepsy medicine, 7 experienced dizziness, and 93 did not.

For every 100 people with drug-generalised tonic-clonic seizures who took a placebo with their usual epilepsy medicine, 7 experienced dizziness, and 93 did not.
Drowsiness
For every 100 people with drug-resistant generalised tonic-clonic seizures who took lamotrigine with their usual epilepsy medicine, 3 experienced drowsiness, and 97 did not.
For every 100 people with drug-resistant generalised tonic-clonic seizures who took a placebo with their usual epilepsy medicine, 1 experienced drowsiness, and 99 did not.

Fatigue (feeling very tired in body and mind)
For every 100 people with drug-resistant generalised tonic-clonic seizures who took lamotrigine with their usual epilepsy medicine, 2 experienced fatigue, and 98 did not.
For every 100 people with drug-resistant generalised tonic-clonic seizures who took a placebo with their usual epilepsy medicine, 2 experienced fatigue, and 98 did not.

Fever
For every 100 people with drug-resistant generalised tonic-clonic seizures who took lamotrigine with their usual epilepsy medicine, 4 experienced fever, and 96 did not.
For every 100 people with drug-resistant generalised tonic-clonic seizures who took a placebo with their usual epilepsy medicine, 5 experienced fever, and 95 did not.
Headache

For every 100 people with drug-resistant generalised tonic-clonic seizures who took lamotrigine with their usual epilepsy medicine, 15 experienced headache, and 85 did not. For every 100 people with drug-resistant generalised tonic-clonic seizures who took a placebo with their usual epilepsy medicine, 20 experienced headache, and 80 did not.

Nausea (feeling sick)

For every 100 people with drug-resistant generalised tonic-clonic seizures who took lamotrigine with their usual epilepsy medicine, 8 experienced nausea, and 92 did not. For every 100 people with drug-resistant generalised tonic-clonic seizures who took a placebo with their usual epilepsy medicine, 5 experienced nausea, and 95 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 (loose stools)
- 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.

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):

www.cochrane.org/CD007783/EPILEPSY_lamotrigine-add-therapy-drug-resistant-generalised-tonic-clonic-seizures