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

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

Who and what is rufinamide for?

Rufinamide is for people who have epilepsy, who are still having seizures, despite taking one or more epilepsy medicines. Rufinamide 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 rufinamide 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 1759 people. All of these people had drug-resistant focal epilepsy and were between 4 and 80 years old. This Patient Decision aid is, therefore, for children and adults with drug-resistant focal epilepsy.

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

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 rufinamide with their usual epilepsy medicine, 26 had a 50% or greater reduction in seizures, and 74 did not.

In comparison, for every 100 people with drug-resistant focal epilepsy who took a placebo with their usual epilepsy medicine, 14 had a 50% or greater reduction in seizures and 86 did not.

These numbers show that people taking rufinamide were roughly 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 certain that these findings are accurate.
Seizure freedom

For every 100 people with drug-resistant focal epilepsy who took \textit{rufinamide} with their usual epilepsy medicine, 14 became seizure-free, and 86 did not.

In comparison, for every 100 people with drug-resistant focal epilepsy who took a \textit{placebo} with their usual epilepsy medicine, 10 became seizure-free and 90 did not.

These numbers show that people taking \textit{rufinamide} were slightly more likely to become seizure free than people taking a \textit{placebo}.

How confident are we that these findings are correct?

We graded the evidence for seizure freedom to be of moderate certainty. This means we are fairly certain that these findings are accurate.
What are the main risks of taking rufinamide?

Like any medicine, rufinamide 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 focal epilepsy who took rufinamide with their usual epilepsy medicine, 21 withdrew from the trials, and 79 did not.

For every 100 people with drug-resistant focal epilepsy who took a placebo with their usual epilepsy medicine, 11 withdrew from the trials, and 89 did not.

These numbers show that people taking rufinamide were nearly 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 rufinamide?

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.

Dizziness

For every 100 people with drug-resistant focal epilepsy who took rufinamide with their usual epilepsy medicine, 27 experienced dizziness, and 73 did not.

For every 100 people with drug-resistant focal epilepsy who took a placebo with their usual epilepsy medicine, 11 experienced dizziness, and 89 did not.

Double vision

For every 100 people with drug-resistant focal epilepsy who took rufinamide with their usual epilepsy medicine, 11 experienced double vision, and 89 did not.

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

For every 100 people with drug-resistant focal epilepsy who took **rufinamide** with their usual epilepsy medicine, 16 experienced drowsiness, and 84 did not.

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

**Fatigue (feeling very tired in body and mind)**

For every 100 people with drug-resistant focal epilepsy who took **rufinamide** with their usual epilepsy medicine, 16 experienced fatigue, and 84 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 **rufinamide** with their usual epilepsy medicine, 27 experienced headache, and 73 did not.

For every 100 people with drug-resistant focal epilepsy 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 focal epilepsy who took **rufinamide** with their usual epilepsy medicine, 15 reported nausea, and 85 did not.

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

**Vomiting (being sick)**

For every 100 people with drug-resistant focal epilepsy who took **rufinamide** with their usual epilepsy medicine, 15 experienced vomiting, and 85 did not.

For every 100 people with drug-resistant focal epilepsy who took a **placebo** with their usual epilepsy medicine, 5 experienced vomiting, and 95 did not.
These numbers show that people taking rufinamide were more likely to experience: headache, dizziness, drowsiness, vomiting, nausea, fatigue, and double vision than people taking a placebo.

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

There is more information about the possible side-effects associated with taking rufinamide on this page.

We have taken this information from the Summary of Product Characteristics* for rufinamide. This was produced by Eisai, the manufacturer of inovelon, and was approved by the European Medicines Agency (EMA).

Very common side-effects

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

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

Common side-effects

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

- abnormal gait (a change to the way that a person normally walks)
- acne
- anxiety
- back pain
- blurred vision
- bruising
- constipation (difficulty passing stools)
- convulsions/seizures
- diarrhoea (loose stools)
- difficulty walking
- head injury (as a result of accidental injury during a seizure)
- indigestion
- infections including ear infection, flu, nasal congestion, chest infection

• infrequent periods
• insomnia (difficulty sleeping)
• loss or change in appetite
• nose bleeds
• rash
• stomach pain
• trembling
• unusual eye movements

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 rufinamide, 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.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD011772.pub3/full#CD011772-abs-0002