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

Trusted evidence.
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Tiagabine add-on therapy for drug-resistant focal epilepsy

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

Who and what is tiagabine for?

Tiagabine is for people who have epilepsy, who are still having seizures, despite taking one or more epilepsy medicines. Tiagabine 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 tiagabine 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 948 people. All of these people had drug-resistant focal epilepsy and were between 12 and 77 years old. This Patient Decision aid is, therefore, for adolescents and adults with drug-resistant focal epilepsy.

In these trials, people took either tiagabine 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 January 2019.
What are the main benefits of using tiagabine?

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 tiagabine with their usual epilepsy medicine, 22 had a 50% or greater reduction in seizures, and 78 did not.

In comparison, for every 100 people with drug-resistant focal epilepsy who took a placebo with their usual epilepsy medicine, 7 had a 50% or greater reduction in seizures and 93 did not.

These numbers show that people taking tiagabine were three times more likely to have a 50% reduction in seizures than 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 high certainty. This means we are confident that these findings are accurate.
What are the main risks of taking tiagabine?

Like any medicine, tiagabine 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 tiagabine with their usual epilepsy medicine, 20 withdrew from the trials, and 80 did not.

For every 100 people with drug-resistant 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 tiagabine 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 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 tiagabine?

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)

<table>
<thead>
<tr>
<th>For every 100 people with drug-resistant focal epilepsy who took tiagabine with their usual epilepsy medicine, 7 experienced ataxia</th>
<th>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.</th>
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### Dizziness

| For every 100 people with drug-resistant focal epilepsy who took tiagabine with their usual epilepsy medicine, 27 experienced dizziness, and 73 did not. | For every 100 people with drug-focal epilepsy who took a placebo with their usual epilepsy medicine, 16 experienced dizziness, and 84 did not. |
Drowsiness (feeling sleepy)

For every 100 people with drug-resistant focal epilepsy who took **tiagabine** with their usual epilepsy medicine, 18 experienced drowsiness, and 82 did not.

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

Headache

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

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

Fatigue (feeling very tired in body and mind)

For every 100 people with drug-resistant focal epilepsy who took **tiagabine** with their usual epilepsy medicine, 21 experienced fatigue, and 79 did not.

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

For every 100 people with drug-resistant epilepsy who took **tiagabine** with their usual epilepsy medicine, 14 reported infection, and 86 did not.

For every 100 people with drug-resistant epilepsy who took **placebo** with their usual epilepsy medicine, 14 reported infection, and 86 did not.

Nausea (feeling sick)

For every 100 people with drug-resistant focal epilepsy who took **tiagabine** with their usual epilepsy medicine, 12 experienced nausea, and 88 did not.

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

Nervousness

For every 100 people with drug-resistant focal epilepsy who took **tiagabine** with their usual epilepsy medicine, 10 reported feeling nervous, and 90 did not.

For every 100 people with drug-resistant focal epilepsy who took **placebo** with their usual epilepsy medicine, 1 reported feeling nervous, and 99 did not.
Tremor

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

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

These numbers show that people taking tiagabine were more likely to experience: dizziness and tremor, than people taking a placebo.

The most common side-effect experienced by people taking tiagabine was dizziness.
Is there any more information about side effects available?

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

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

Very common side-effects

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

- feeling nervous
- dizziness
- tremor
- feeling sick (nausea)
- feeling tired

Common side-effects

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

- problems with concentration
- depressed mood
- strong, heightened emotions (such as feeling very angry) or exaggerated expressions of emotion (such as uncontrollable laughing or crying)
- feeling confused
- insomnia (trouble sleeping)
- being hostile or aggressive
- ataxia (problems with balance, co-ordination and speech)
- abnormal gait (a change to the way that a person normally walks)
- problems speaking (speech disorder)
- blurred vision
- diarrhoea
- being sick (vomiting) and stomach cramps (abdominal pain)
- muscle twitching
- accidental injury

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 tiagabine, 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_tiagabine-add-therapy-drug-resistant-focal-epilepsy