

Antiepileptic medicines: risk of suicidal thoughts and behaviour

Questions & Answers

What are antiepileptic medicines used for?

Antiepileptic medicines are used to treat epilepsy. Some of them are also used to treat other disorders (conditions) such as schizophrenia, bipolar disorder, anxiety, and nerve pain.

Why was there a review of their safety in relation to the risk of suicidal thoughts and behaviour?

Over the past few years, reviews of available evidence have identified an increased risk of suicidal thoughts and behaviour in people who take some antiepileptic medicines. These medicines were topiramate, levetiracetam, vigabatrin, and zonisamide. Product information for healthcare professionals and patients was updated accordingly. Furthermore, information about a risk of depressed mood or depression has been included in the prescribing information for some antiepileptic medicines—carbamazepine, gabapentin, levetiracetam, oxcarbazepine, pregabalin, tiagabine, topiramate, vigabatrin, and zonisamide.

However, the available evidence had not been assessed for all antiepileptic medicines. Therefore, a European review took place. In the USA, the Food and Drug Administration has also investigated the potential risk of suicidal thoughts and behaviour with antiepileptic medicines.

What kind of analysis was done and by whom?

To analyse evidence for the potential link between these medicines and the risk of having suicidal thoughts or suicidal behaviour, medicines regulatory authorities throughout the European Union gathered and analysed information from clinical trials of these medicines, information reported in the scientific literature, and from databases that recorded spontaneous reports of side-effects in people who have taken an antiepileptic medicine.

Which medicines were assessed?

The following antiepileptic medicines were assessed in the European review:

- carbamazepine
- divalproex sodium
- felbamate
- gabapentin
- lamotrigine
- levetiracetam
- oxcarbazepine
- pregabalin
- tiagabine
- topiramate
- vigabatrin
- zonisamide

What are the main findings?

The findings suggest that treatment with antiepileptic medicines is associated with a small risk of suicidal thoughts and behaviour, but this risk does not outweigh the benefits of these treatments in their authorised indications. They also show that the risk applies to all antiepileptic medicines and may occur as early as 1 week after starting treatment.

What will happen as a result?

The product information for healthcare professionals and patients for all antiepileptic medicines that are authorised in the European Union will be updated. The new information will reflect current evidence for the potential risk of suicidal thoughts and behaviour and advise that patients should be monitored for signs of suicidal thoughts, or suicidal behaviour throughout treatment.

How do the antiepileptic medicines increase the risk of suicidal thoughts or behaviour?

At present, it is not known how antiepileptic medicines increase the risk of having suicidal thoughts or behaviour. Therefore, it is not possible to say which medicines are not associated with an increased risk.

I am currently taking an antiepileptic medicine. What shall I do?

There is no need to stop treatment or change your antiepileptic medicine on the basis of this new information. Talk to your doctor if you have any concerns about your treatment, and attend your scheduled check-ups. You or, where appropriate, your carer should contact your doctor if either of you notice that you develop any mood changes, distressing thoughts, or feelings about suicide or harming yourself at any point during treatment.

Should I switch to another antiepileptic?

There is no need to change your antiepileptic medicine on the basis of this new information. The available evidence does not show clearly whether the risk of suicidal thoughts and behaviour differs between antiepileptic medicines. Therefore it cannot be said for certain that particular antiepileptic medicines are not associated with an increased risk of suicidal thoughts and behaviour.

It is very important that you do not stop or change your antiepileptic medicine(s) unless you have first discussed this with your doctor.