

## Antiepileptics

### Risk of suicidal thoughts and behaviour

#### **Key Statement**

A European review of antiepileptic medicines has concluded that any medicine in this class may be associated with a small risk of suicidal thoughts and behaviour. This review assessed clinical trial data, spontaneous reports of adverse drug reactions received after marketing, and literature reports of suicidal thoughts and behaviour associated with the following antiepileptic medicines: carbamazepine; divalproex sodium; felbamate; gabapentin; lamotrigine; levetiracetam; oxcarbazepine; pregabalin; tiagabine; topiramate; vigabatrin; and zonisamide.

On the basis of the available evidence it is not possible to say whether the risk of suicidal thoughts and behaviour differs between antiepileptic medicines. Furthermore, the mechanism by which antiepileptic medicines may increase the risk of a patient having suicidal thoughts and behaviour is not known and therefore it is not possible to identify which medicines might not be associated with increased risk.

The US Food and Drug Administration has also investigated the risk of suicidal thoughts and behaviour with antiepileptic medicines and their findings are consistent with those of the European review. For further information about the US review, see <http://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-4372b1-01-FDA.pdf>

Product information for all antiepileptic medicines will be updated to reflect current evidence for the potential risk of suicidal thoughts and behaviour:

#### *Key information:*

- Treatment with antiepileptic medicines is associated with a small risk of suicidal thoughts and behaviour; available data suggest that the increased risk applies to all antiepileptic medicines and may be seen as early as 1 week after starting treatment.
- There is no need to stop treatment or change your antiepileptic medicine on the basis of this new information. Anyone who is concerned about their treatment should talk to their doctor.
- Patients should be monitored for signs of depression or suicidal thoughts and behaviour throughout treatment, and should be referred for appropriate treatment if necessary.
- Patients and caregivers should be advised to be alert to any mood changes, distressing thoughts, or feelings about suicide or harming themselves at any point during treatment. Patients should be advised to seek medical advice if they develop such thoughts.