

Antiepileptics and suicidal behaviour

Final SPC and PIL wording agreed by PhVWP July 2008

Summary of Product Characteristics

“Section 4.4 Special Warnings and Precautions for Use

Suicidal ideation and behaviour have been reported in patients treated with anti-epileptic agents in several indications. A meta-analysis of randomised placebo controlled trials of anti-epileptic drugs has also shown a small increased risk of suicidal ideation and behaviour. The mechanism of this risk is not known and the available data do not exclude the possibility of an increased risk for <drug substance>.

Therefore patients should be monitored for signs of suicidal ideation and behaviours and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge.”

Package Leaflet

“Section 2 Before you take X

Take special care with

A small number of people being treated with anti-epileptics such as << drug substance >> have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.”

The following timetable is proposed for the implementation:

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| 15 September 2008 | Variation applications requested by NCAs |
| 15 October 2008 | Variation applications submitted by MA holders |
| 15 January 2009 | Variation applications approved by NCAs |
| 15 April 2009 | Updated PLs into new production batches. |