

Vigabatrin and MRI abnormalities and movement disorders

Final SPC and PL wording agreed by PhVWP October 2009

*Doc. Ref.: CMDh/PhVWP/009/2009
October 2009*

SUMMARY OF PRODUCT CHARACTERISTICS

Section 4.4.

Cases of abnormal brain MRI findings have been reported, in particular in young infants treated for infantile spasms with high doses of vigabatrin. The clinical significance of these findings is currently unknown.

Movement disorders including dystonia, dyskinesia and hypertonia have been reported in patients treated for infantile spasms. The benefit/risk of vigabatrin should be evaluated on an individual patient basis. If new movement disorders occur during treatment with vigabatrin, consideration should be given to dose reduction or a gradual discontinuation of treatment.

Section 4.8.

*Nervous system disorders
Frequency: Not known*

Cases of brain MRI abnormalities have been reported (see section 4.4).

Movement disorders, including dystonia, dyskinesia and hypertonia have been reported, either alone or in association with abnormalities in MRI (see section 4.4).

PACKAGE LEAFLET

Section 2. Take special care with

“Movement disorders have been seen in young infants treated for infantile spasm (West syndrome). If you observe unusual movement disorders in the child, consult the doctor who will decide if it is necessary to consider changing the treatment”

Section 4. Possible side effects

“Side effects with unknown frequency”:

“Movement disorders in young infants treated for infantile spasm”