

## **Oxcarbazepine**

### **RECOMMENDED CHANGES TO THE PRODUCT INFORMATION**

The following changes to the product information of medicinal products containing the active substance oxcarbazepine are recommended:

#### **Summary of product characteristics**

- Section 4.4

Three warnings should be added as follows:

Due to the risk of hypothyroidism, thyroid function monitoring is recommended in the pediatric age group while on Trileptal therapy.

In patients with impaired renal function (creatinine clearance less than 30 mL/min), caution should be exercised during Trileptal treatment especially with regard to the starting dose and up titration of the dose.

The risk of seizure aggravation is seen especially in children but may also occur in adults. In case of seizure aggravation, Trileptal should be discontinued.

- Section 4.8

The following adverse reaction should be added under the SOC "nervous system disorders" with a frequency of "not known":

"Speech disorders (including dysarthria); more frequent during up titration of Trileptal dose"

#### **Package leaflet**

The package leaflet should be updated in accordance with the SmPC amendments.