



Bundesamt für  
Sicherheit im  
Gesundheitswesen  
**BASG**

Unternehmen/Frau/Herr  
Organisationseinheit (optional)  
(z. H.) Vorname Nachname  
Straße  
PLZ Ort

**Datum:** 10.06.2022  
**Kontakt:** Ing. Veronika Heimlich, B.Sc.  
**Tel:** +43 50555 36247  
**E-Mail:** pv-implementation@basg.gv.at  
**Unser Zeichen:** PHV-101032443-A-220609  
**Ihr Zeichen:**

---

### **PHV-issue: Gabapentin**

Sehr geehrte Damen und Herren,  
Aufgrund eines Outcomes of PSUSA follow-up via variation (PSUFU), dessen Ergebnis durch das CMDh bestätigt wurde, kommt es zu der Änderung der Genehmigungen für das Inverkehrbringen der Arzneimittel mit dem Wirkstoff Gabapentin.

(siehe: <http://www.hma.eu/611.html>)

## Auszug aus der CMDh recommendation for gabapentin containing products:

### Final recommendations/Outcome of the (WS) variation procedure

#### Conclusion:

It is therefore agreed to update SmPC section 4.4 as follows:

#### SmPC section 4.4

##### Suicidal ideation and behavior

Suicidal ideation and behaviour have been reported in patients treated with antiepileptic 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 gabapentin. **Cases of suicidal ideation and behaviour have been reported observed in patients treated with gabapentin in the post-marketing setting experience (see section 4.8).**

**Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge.** Patients should be monitored for signs of suicidal ideation and behaviour and appropriate treatment should be considered. **Discontinuation of gabapentin treatment should be considered in case of suicidal ideation and behavior in patients with signs of suicidal ideation and behavior might be necessary. The decision whether gabapentin should be discontinued in case of suicidal ideation and behavior should be made on an individual basis.** Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge.

#### Assessment of MAH's response to PRAC recommendation 2:

The MAH will comply with the recommendation to update the label as proposed by the RMS, i.e. the addition of 'suicidal ideation' to **Section 4.8 Undesirable effects** of the SmPC and the addition of 'suicidal thoughts' to **Section 4** of the PL.

#### PRAC recommendation 2:

**SmPC section 4.8 Undesirable effects:** Psychiatric disorders

Frequency not known: **suicidal ideation**

**PL section 4:** Frequency not known: ~~thoughts of killing yourself~~ **suicidal thoughts**