



יולי 2022

פייזר פי אף אי פרמצבטיקה ישראל בע"מ  
רח' שנקר 9, ת.ד. 12133  
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טל: 972-9-9700500 פקס: 972-9-9700501

רופא/ה, רוקח/ת נכבד/ה,

ברצוננו להודיעך על עדכון בעלון לרופא ולצרכן של **NEURONTIN 400& 300 MG** :

GABAPENTIN 300 & 400 mg

Epilepsy:

- Gabapentin is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults and adolescents (age 12 and up) with epilepsy.
- Treatment of neuropathic pain
- Gabapentin is indicated for the treatment of neuropathic pain in diabetic neuropathy or postherpetic neuropathy (neuralgia) in adults.

**להלן העדכונים העיקריים בעלון לרופא NEURONTIN 400& 300 MG:**

#### 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

##### Suicidal ideation and behaviour

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. **Cases of suicidal ideation and behaviour have been observed in patients treated with gabapentin in the post-marketing experience (see section 4.8).** ~~and the available data do not exclude the possibility of an increased risk for gabapentin.~~

**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 behaviours and appropriate treatment should be considered. **Discontinuation of gabapentin treatment should be considered in case of suicidal ideation and behaviour.**

~~Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge.~~

#### 4.8 Undesirable effects

The adverse reactions observed during clinical studies conducted in epilepsy (adjunctive and monotherapy) and neuropathic pain have been provided in a single list below by class and frequency: very common ( $\geq 1/10$ ); common ( $\geq 1/100$  to  $< 1/10$ ); uncommon ( $\geq 1/1,000$  to  $< 1/100$ ); rare ( $\geq 1/10,000$  to  $< 1/1,000$ ); very rare ( $< 1/10,000$ ). Where an adverse reaction was seen at different frequencies in clinical studies, it was assigned to the highest frequency reported.

Additional reactions reported from post-marketing experience are included as frequency Not known (cannot be estimated from the available data) in italics in the list below.

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Psychiatric disorders	
Common	hostility, confusion and emotional lability, depression, anxiety, nervousness, thinking abnormal
Uncommon	agitation
Not known	suicidal ideation, hallucinations

**להלן העדכונים העיקריים בעלון לצרכן עבור NEURONTIN 400& 300 MG:**

4. תופעות לוואי

**תופעות לוואי שדווחו לאחר שיווק התרופה ושכיחותן אינה ידועה:**

- מחשבות אובדניות

השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה. העלונים המעודכנים זמינים באתר משרד הבריאות.

<https://israeldrugs.health.gov.il/#!/byDrug>

לחילופין, לקבלת עלון מלא מודפס ניתן לפנות לחברת פייזר פרמצבטיקה ישראל בע"מ, שנקר 9, ת.ד. 12133 הרצליה פיתוח, 46725.

בברכה,  
אורטל עבודי  
רוקחת ממונה