



ינואר 2024

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רופא/ה, רוקח/ת נכבד/ה,

ברצוננו להודיעך על עדכון בעלון לרופא בלבד 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.

#### 4.6 FERTILITY, PREGNANCY AND LACTATION

*Risk related to epilepsy and antiepileptic drugs (AEDs) medicinal products in general*

Specialist advice regarding the potential risk to a foetus caused by both seizures and antiepileptic treatment should be given to women of childbearing potential, and especially to women planning for pregnancy and women who are pregnant. The need for antiepileptic treatment should be reviewed when a woman is planning to become pregnant. In women being treated for epilepsy, no sudden discontinuation of antiepileptic therapy should be undertaken as this may lead to breakthrough seizures, which could have serious consequences for both mother and child. Monotherapy should be preferred whenever possible because therapy with multiple AEDs could be associated with a higher risk of congenital malformations than monotherapy, depending on the antiepileptics used.

The risk of birth defects is increased by a factor of 2—3 in the offspring of mothers treated with an antiepileptic medicinal product. Most frequently reported are cleft lip, cardiovascular malformations and neural tube defects. Multiple antiepileptic drug therapy may be associated with a higher risk of congenital malformations than monotherapy, therefore it is important that monotherapy is practiced whenever possible. Specialist advice should be given to women who are likely to become pregnant or who are of childbearing potential and the need for antiepileptic treatment should be reviewed when a woman is planning to become pregnant. No sudden discontinuation of antiepileptic therapy should be undertaken as this may lead to breakthrough seizures, which could have serious consequences for both mother and child. Developmental delay in children of mothers with epilepsy has been observed rarely. It is not possible to differentiate if the developmental delay is caused by genetic, social factors, maternal epilepsy or the antiepileptic therapy.

*Risk related to gabapentin*

Gabapentin crosses the human placenta.

Data from a Nordic observational study of more than 1700 pregnancies exposed to gabapentin in the first trimester showed no higher risk of major congenital malformations among the children exposed to gabapentin compared to the unexposed children and <sup>2</sup> compared to the children exposed to pregabalin, lamotrigine and pregabalin or lamotrigine. Likewise, no increased risk of neurodevelopmental disorders was observed in children exposed to gabapentin during pregnancy.

There was limited evidence of a higher risk of low birth weight and preterm birth but not of stillbirth, small for gestational age, low Apgar score at 5 minutes and microcephaly in newborns of women exposed to gabapentin.

Studies in animals have shown reproductive toxicity (see section 5.3).

Gabapentin can be used during the first trimester of pregnancy if clinically needed.

There are no or limited amount of data from the use of gabapentin in pregnant women.

Studies in animals have shown reproductive toxicity (see section 5.3). The potential risk for humans is unknown. Gabapentin should not be used during pregnancy unless the potential benefit to the mother clearly outweighs the potential risk to the foetus.

No definite conclusion can be made as to whether gabapentin is causally associated with an increased risk of congenital malformations when taken during pregnancy, because of epilepsy itself and the presence of concomitant antiepileptic medicinal products during each reported pregnancy.

Neonatal withdrawal syndrome has been reported in newborns exposed in utero to gabapentin. Co-exposure to gabapentin and opioids during pregnancy may increase the risk of neonatal withdrawal syndrome. Newborns should be monitored carefully.

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 פיזר פרמצבטיקה ישראל בע"מ, שנקר 9, ת.ד. 12133 הרצליה פיתוח, 46725.

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