הודעה על החמרה (מידע בטיחות) בעלון לרופא
(מעודכן 3102.50)

תאריך _____July 13, 2015 _____

שם תכשיר באנגלית ומספר הרישום

GABAPENTIN TEVA Capsules300 mg: 119 46 29956 00; 119 46 29956 01

GABAPENTIN TEVA Capsules 400 mg: 119 47 29937 00; 119 47 29937 01

GABAPENTIN TEVA Tablets 600 mg: 146.53.32979.00; 146.53.32979.01

GABAPENTIN TEVA Tablets 800 mg: 146.54.32980.00; 146.54.32980.01

שם בעל הרישום טבע תעשיות פרמצבטיות בע"מ ת.ד.: 3190 פ"ת_____

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
טקסט חדש	**טקסט נוכחי**	**פרק בעלון**
		Indication
		contraindications
Dosage adjustment in patients undergoing hemodialysis: For patients undergoing hemodialysis who have never received gabapentin, a loading dose of 300 to 400 mg is recommended, then 200 to 300 mg of gabapentin following each 4 hours of hemodialysis is recommended. On dialysis-free days, there should be no treatment with gabapentin. For renally impaired patients undergoing haemodialysis, the maintenance dose of gabapentin should be based on the dosing recommendations found in Table 2. In addition to the maintenance dose, an additional 200 to 300 mg dose following each 4-hour haemodialysis treatment is recommended.		**Posology, dosage & administration**
Although there is no evidence of rebound seizures with gabapentin, abrupt withdrawal of anticonvulsants in epileptic patients may precipitate status epilepticus. As with other antiepileptics, attempts to withdraw concomitant antiepileptics in treatment refractive patients on more than one antiepileptic, in order to reach gabapentin monotherapy have a low success rate.	Although there is no evidence of rebound seizures with gabapentin, abrupt withdrawal of anticonvulsants in epileptic patients may precipitate status epilepticus.	**Special Warnings and Special Precautions for Use**
		Information for patients
		Overdosage
Gabapentin steady-state pharmacokinetics are similar for healthy subjects and patients with epilepsy receiving these antiepileptic agents. ***Gabapentin/OpioidsMorphine:*** There are spontaneous and literature case reports of respiratory depression and/or sedation associated with gabapentin and opioid use. In some of these reports, the authors considered this a particular concern with the combination of gabapentin and opioids, especially in elderly patients.		**Interaction with Other Medicaments and Other Forms of Interaction**

Cases of abuse and dependence have been reported in the post-marketing database. Carefully evaluate patients for a history of drug abuse and observe them for possible signs of gabapentin abuse e.g. drug-seeking behaviour, dose escalation, development of tolerance. ~~The abuse and dependence potential of gabapentin had not been evaluated in human studies.~~	The abuse and dependence potential of gabapentin had not been evaluated in human studies.	**Drug abuse and dependence**
		Fertility, pregnancy and Lactation
False positive readings may be obtained in the semi-quantitative determination of total urine protein by dipstick tests. It is therefore recommended to verify such a positive dipstick test result by methods based on a different analytical principle such as the Biuret method, turbidimetric or dye-binding methods, or to use these alternative methods from the beginning.		**Laboratory tests**
Single List of Compiled Adverse Reactions in Epilepsy (adjunctive and monotherapy) and Neuropathic pain 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 (≥ 1/10); common (≥ 1/100 to< 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 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. Table of adverse reactions **See separate attached list** Under treatment with gabapentin cases of acute pancreatitis were reported. Causality with gabapentin is unclear. In patients on haemodialysis due to end-stage renal failure, myopathy with elevated creatine kinase levels has been reported. Respiratory tract infections, otitis media, convulsions and bronchitis were reported only in clinical studies in children. Additionally, in clinical studies in children, aggressive behaviour and hyperkinesias were reported commonly.		**Adverse events**

Reporting of suspected adverse reactions Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to the Ministry of Health according to the National Regulation by using an online form (http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.health.gov.il) or by email (adr@MOH.HEALTH.GOV.IL).		

Body System	Adverse drug reactions
Infections and infestations	
Very Common	viral infection
Common	pneumonia, respiratory infection, urinary tract infection, infection, otitis media
Blood and the lymphatic system disorders	
Common	leucopenia
Not known	thrombocytopenia
Immune system disorders	
Uncommon	allergic reactions (e.g. urticaria)
Not known	hypersensitivity syndrome, a systemic reaction with a variable presentation that can include fever, rash, hepatitis, lymphadenopathy, eosinophilia, and sometimes other signs and symptoms
Metabolism and Nutrition Disorders	
Common	anorexia, increased appetite
Uncommon	hyperglycemia (most often observed in patients with diabetes)
Rare	hypoglycaemia (most often observed in patients with diabetes)
Not known	hyponatraemia
Psychiatric disorders	
Common	hostility, confusion and emotional lability, depression, anxiety, nervousness, thinking abnormal
Not known	hallucinations
Nervous system disorders	
Very Common	somnolence, dizziness, ataxia
Common	convulsions, hyperkinesias, dysarthria, amnesia, tremor, insomnia, headache, sensations such as paresthesia, hypaesthesia, coordination abnormal, nystagmus, increased, decreased, or absent reflexes
Uncommon	hypokinesia, mental impairment
Rare	loss of consciousness
Not known	other movement disorders (e.g. choreoathetosis, dyskinesia, dystonia)
Eye disorders	
Common	visual disturbances such as amblyopia, diplopia
Ear and Labyrinth disorders	
Common	vertigo
Not known	*tinnitus*
Cardiac disorders	
Uncommon	palpitations
Vascular disorders	
Common	hypertension, vasodilatation
Respiratory, thoracic and mediastinal disorders	
Common	dyspnoea, bronchitis, pharyngitis, cough, rhinitis
Gastrointestinal disorders	
Common	vomiting, nausea, dental abnormalities, gingivitis, diarrhoea, abdominal pain, dyspepsia, constipation, dry mouth or throat, flatulence

Not known	pancreatitis
Hepatobiliary disorders	
Not known	hepatitis, jaundice
Skin and subcutaneous tissue disorders	
Common	facial oedema, purpura most often described as bruises resulting from physical trauma, rash, pruritus, acne
Not known	*Stevens-Johnson syndrome, angioedema, erythema multiforme, alopecia, drug rash with eosinophilia and systemic symptoms (see section 4.4)*
Musculoskeletal and connective tissue disorders	
Common	arthralgia, myalgia, back pain, twitching
Not known	rhabdomyolysis, myoclonus
Renal and urinary disorder	
Not known	acute renal failure, incontinence
Reproductive system and breast disorders	
Common	impotence
Not known	breast hypertrophy, gynaecomastia, sexual dysfunction (including changes in libido, ejaculation disorders and anorgasmia)
General disorders and administration site conditions	
Very Common	fatigue, fever
Common	peripheral oedema, abnormal gait, asthenia, pain, malaise, flu syndrome
Uncommon	generalized oedema
Not known	withdrawal reactions (mostly anxiety, insomnia, nausea, pains, sweating), chest pain. Sudden unexplained deaths have been reported where a causal relationship to treatment with gabapentin has not been established.
Investigations	
Common	WBC (white blood cell count) decreased, weight gain
Uncommon	elevated liver function tests SGOT (AST), SGPT (ALT) and bilirubin
Not known	blood creatine phosphokinase increased
Injury and poisoning	
Common	accidental injury, fracture, abrasion
Uncommon	fall