ינואר 2024

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

חברת איי.אל.מדי-מרקט בע"מ מודיעה על העדכונים הבאים בעלון לרופא של התכשיר:

LEVEBON 100 MG/ML
לוובון 100 מ"ג/מ"ל

חומר פעיל: LEVETIRACETAM 100 MG / 1 ML

צורת מינון: CONCENTRATE FOR SOLUTION FOR INFUSION

עדכונים בעלון לרופא

התוויה כפי שאושרה בתעודת הרישום:

LEVEBON is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalisation in adults and adolescents from 16 years of age with newly diagnosed epilepsy.

LEVEBON is indicated as adjunctive therapy.

• in the treatment of partial onset seizures with or without secondary generalisation in adults, adolescents and children from 4 years of age with epilepsy.

• in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy.

• in the treatment of primary generalised tonic-clonic seizures in adults and adolescents from 12 years of age with Idiopathic Generalised Epilepsy.

LEVEBON concentrate is an alternative for patients when oral administration is temporarily not feasible.

ברצוננו להודיע שהעלון לרופא עודכן. בהודעה זו כלולים העדכונים המהותיים בלבד. החמרות מסומנות בצהוב, תוספת טקסט מסומנת בקו תחתון, מחיקת טקסט מסומנת בקו חוצה.

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4.4 Special warnings and precautions for use

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Worsening of seizures

As with other types of antiepileptic drugs, levetiracetam may rarely exacerbate seizure frequency or severity. This paradoxical effect was mostly reported within the first month after levetiracetam initiation or increase of the dose, and was reversible upon drug discontinuation or dose decrease. Patients should be advised to consult their physician immediately in case of aggravation of epilepsy.

Lack of efficacy or seizure worsening has been reported in patients with epilepsy associated with sodium voltage-gated channel alpha subunit 8 (SCN8A) mutations.

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Tabulated list of adverse reactions

Adverse reactions reported in clinical studies (adults, adolescents, children and infants > 1 month) and from post-marketing experience are listed in the following table per System Organ Class and per frequency. Adverse reactions are presented in the order of decreasing seriousness and their frequency is defined as follows: 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) and very rare (<1/10,000).

MedDRA SOC	Frequency category				
	Very common	Common	Uncommon	Rare	Very rare
Infections and infestations	*Nasopharyngitis*			*Infection*	
Blood and lymphatic system disorders			Thrombocytopenia, leukopenia	Pancytopenia, neutropenia, agranulocytosis	
Immune system disorders				Drug reaction with eosinophilia and systemic symptoms (DRESS), Hypersensitivity (including angioedema and anaphylaxis)	
Metabolism and nutrition disorders		Anorexia	Weight decrease, weight increase	Hyponatraemia	
Psychiatric disorders		Depression, hostility/ aggression, anxiety, insomnia, nervousness/ irritability	Suicide attempt, suicidal ideation, psychotic disorder, abnormal behaviour, hallucination, anger, confusional state, panic attack, affect lability/mood swings, agitation	Completed suicide, personality disorder, thinking abnormal, delirium	Obsessive compulsive disorder**
Nervous system disorders	Somnolence, headache	Convulsion, balance disorder, dizziness, lethargy, tremor	Amnesia, memory impairment, coordination abnormal/ataxia, paraesthesia, disturbance in attention	Choreoathetosis, dyskinesia, hyperkinesia, gait disturbance, encephalopathy, seizures aggravated	
Eye disorder			Diplopia, vision blurred		
Ear and labyrinth disorders		Vertigo			
Cardiac disorders				Electrocardiogram QT prolonged	

Respiratory, thoracic and mediastinal disorders		Cough			
Gastrointestinal disorders		Abdominal pain, diarrhoea, dyspepsia, vomiting, nausea		Pancreatitis	
Hepatobiliary disorders			Liver function test abnormal	Hepatic failure, hepatitis	
Renal and Urinary Disorders				Acute kidney injury	
Skin and subcutaneous tissue disorders		Rash	Alopecia, eczema, pruritus,	Toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme	
Musculoskeletal and connective tissue disorders			Muscular weakness, myalgia	Rhabdomyolysis and blood creatine phosphokinase increased*	
General disorders and administration site conditions		Asthenia/fatigue			
Injury, poisoning and procedural complications			Injury		

* Prevalence is significantly higher in Japanese patients when compared to non-Japanese patients. Evidence also suggests a possible predisposition of the Japanese population to neuroleptic malignant syndrome (NMS).
**Very rare cases of development of obsessive-compulsive disorders (OCD) in patients with underlying history of OCD or psychiatric disorders have been observed in post-marketing surveillance.
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העלון לרופא מצורף להודעה זו וכן נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות https://israeldrugs.health.gov.il .

ניתן לקבל את העלון מודפס ע"י פניה לבעל הרישום, חברת איי.אל.מדי-מרקט בע"מ.

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