



ספטמבר 2023

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

חברת פרופארם בע"מ מודיעה על העדכונים הבאים בעלון לרופא של התכשיר:

LEVETIRACETAM ALTAN 100 MG/ML

לבטיראצטם אלטן 100 מ"ג/מ"ל

חומר פעיל: LEVETIRACETAM 100MG/ML
צורת מינון: CONCENTRATE FOR SOLUTION FOR INFUSION
עדכונים בעלון לרופא

התוויה כפי שאושרה בתעודת הרישום:

Levetiracetam Altan 100 mg/ml is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalization in adults and adolescents from 16 years of age with newly diagnosed epilepsy.

Levetiracetam Altan 100 mg/ml is indicated as adjunctive therapy

-in the treatment of partial onset seizures with or without secondary generalization in adults, adolescents patients 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 generalized tonic-clonic seizures in adults and adolescents from 12 years of age with Idiopathic Generalized Epilepsy.

Levetiracetam Altan 100 mg/ml is an alternative for patients when oral administration is temporarily not feasible.

ברצונינו להודיע שהעלון לרופא עודכן, בפירוט שלהלן כלולים העדכונים העיקריים בלבד(תוספות /שינויים מסומנים באדום והחמרות/מידע חדש על רקע צהוב):

4.4 Special warnings and precautions for use

[...]

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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4.8 Undesirable effects

[...]

MedDRA SOC	Frequency category				
	Very common	Common	Uncommon	Rare	
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**

*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.

העלון לרופא מצורף להודעה זו וכן נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות.

ניתן לקבל את העלון מודפס ע"י פניה לבעל הרישום, חברת פרופארם בע"מ, טל 04-6294242.

בברכה,

מירי חזן

רוקחת ממונה