



מרץ 2026

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

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

LEVEBON 100 MG/ML לעובון 100 מ"ג/מ"ל

LEVETIRACETAM 100 MG/ ML חומר פעיל:

CONCENTRATE FOR SOLUTION FOR INFUSION צורת מינון:

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 ברקע צהוב, תוספת טקסט מסומנת באדום עם קו תחתון, מחיקת טקסט מסומנת בקו חוצה.

4.6 Fertility, pregnancy and lactation

[...]

Pregnancy

A large amount of post-marketing data on pregnant women exposed to levetiracetam monotherapy (more than 1800, among which in more than 1500 exposure occurred during the 1st trimester) do not suggest an increase in the risk for major congenital malformations. Only limited evidence is available on the neurodevelopment of children exposed to Levetiracetam monotherapy in utero. Data from two observational population-based registry studies undertaken in largely the same dataset from the Nordic countries and including more than 1000 children born to women with epilepsy prenatally exposed to levetiracetam monotherapy. However, current epidemiological studies (on about 100 children) do not suggest an increased risk of autism spectrum neurodevelopmental disorders or intellectual disability compared to children born to women with epilepsy not exposed to an antiepileptic drug in utero. The mean follow-up time of children in the levetiracetam group was shorter than for the group of children non exposed to any antiepileptic drug (e.g. 4.4 years vs 6.8 years in one of the studies).delays

[...]

4.8 Undesirable effects

[...]

MedDRA SOC	Frequency category				Very rare
	Very common	Common	Uncommon	Rare	
Immune system disorders				Drug reaction with eosinophilia and systemic symptoms (DRESS) ⁽¹⁾ , Hypersensitivity (including angioedema and anaphylaxis)	
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 ^{**(2)}

[...]

(1) See description of selected adverse reactions.

(2) 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.

Description of selected adverse reactions

Multiorgan hypersensitivity reactions

Multiorgan hypersensitivity reactions (also known as Drug Reaction with Eosinophilia and Systemic Symptoms, DRESS) have been reported rarely in patients treated with levetiracetam. Clinical manifestations may develop 2 to 8 weeks after starting treatment. These reactions are variable in expression, but typically present with fever, rash, facial oedema, lymphadenopathies, haematologic abnormalities and can be associated with involvement of different organ systems, mostly the liver. If multiorgan hypersensitivity reaction is suspected, levetiracetam should be discontinued.

[...]

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 א.י.אל.מדי-מרקט בע"מ.