פברואר 2025

LEVETIRACETAM ALTAN 100 MG/ML
לבטיראצטם אלטן 100 מ"ג/מ"ל

חומר פעיל: LEVETIRACETAM 100MG/ML

צורת מינון: CONENTRATE FOR SOLUTION FOR INFUSION

עדכונים בעלון לרופא

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

[…]

Excipient with known effect:
Each vial contains 19.10 mg of sodium ~~(as sodium acetate trihydrate and sodium chloride).~~

4.4 Special warnings and precautions for use

[…]

<u>Excipients</u>

This medicinal product contains 2.5 mmol (or 57 mg) sodium per maximum single dose (0.8 mmol (or 19.10 mg) per vial), equivalent to 2.85% of the WHO recommended maximum daily intake of 2 g sodium for an adult. To be taken into consideration by patients on a controlled sodium diet.

4.6 Fertility, pregnancy and lactation

[…]

<u>Pregnancy</u>

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 common	Common	Uncommon	Rare	Very 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)Evidence also suggests a possible predisposition of the Japanese population to neuroleptic malignant syndrome (NMS).

(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.

*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).

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.