

דצמבר 2021

רופא/ה נכבד/ה
רוקח/ת נכבד/ה

ברצוננו להביא לידיעתכם את העדכונים בעלון לרופא של התכשירים (העלון לצרכן נותר ללא שינוי):

Topamax 25 107-55-29031-00
Topamax 25 107-56-29032-00
Topamax 25 107-57-29033-00
Topamax 25 107-58-29034-00

הרשומים להתוויה:

In adjunctive therapy of adults and children (from 2 years) with partial seizures and generalized tonic-clonic seizures.

In adjunctive therapy of seizures with Lennox-Gastaut syndrome in adults and children.

Topamax is indicated as monotherapy in patients with newly diagnosed epilepsy in children aged 7 years and above or for conversion to monotherapy in patients with epilepsy.

Topamax is indicated in adults for the prevention of migraines.

The use of Topamax in the acute treatment of migraine has not been studied.

העדכונים בעלון לרופא מופיעים בסעיפים הבאים:

[...]

4.4 Special warnings and precautions for use

[...]

Metabolic acidosis and sequelae

[...]

Chronic metabolic acidosis in paediatric patients can reduce growth rates. The effect of topiramate on bone-related sequelae has not been systematically investigated in **paediatric or** adult populations. For paediatric patients aged 6 to 15 years a one year, open-label study was conducted (see section 5.1).

[...]

5.1 Pharmacodynamic properties

[...]

Monotherapy Treatment in Patients 6 to 15 Years Old with New or Recent Epilepsy

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A one year, open-label study in paediatric patients aged 6 to 15 years including 63 subjects with recent or new onset of epilepsy was conducted to assess the effects of topiramate (28 subjects) versus levetiracetam on growth, development, and bone mineralisation. Continued growth was observed in both treatment groups but the topiramate group showed statistically significant reductions in mean annual change from baseline in body weight and bone mineral density compared to the levetiracetam group. A similar trend was also observed for height and height velocity but were not statistically significant. Growth-related changes were not clinically significant nor treatment limiting. Other confounding factors cannot be excluded.

העלון לרופא נשלח לפרסום במלואו למאגר התרופות שבאתר משרד הבריאות. כמו כן, ניתן לקבלו מודפס
בפניה אלינו לטלפון 09-9591111.

בברכה,
צפיר כהן
רוקח ממונה