



רופא/ה נכבד/ה, רוקח/ת נכבד/ה,

אוגוסט 2021

הנדון:

Lamictal Dispersible /Chewable Tablets 2 mg
Lamictal Dispersible /Chewable Tablets 5 mg
Lamictal Dispersible /Chewable Tablets 25 mg
Lamictal Dispersible /Chewable Tablets 50 mg
Lamictal Dispersible /Chewable Tablets 100 mg
Lamictal Dispersible /Chewable Tablets 200 mg

חברת גלקסוסמיתקליין (ישראל) בע"מ מבקשת להודיעכם כי העלון לצרכן והעלון לרופא של התכשירים שבנדון עודכנו.

בהודעה זו כלולים השינויים המהותיים בלבד. בעלונים ישנם שינויים נוספים.

טקסט חדש מסומן בקו תחתו. טקסט שנמחק מסומן בקו חציה. טקסט המהווה החמרה מודגש בצהוב.

התוויות:

Epilepsy

(Lamictal Disp/Chewable Tablets: 2MG, 5MG, 25MG, 50MG, 100MG, 200MG)

Adults and adolescents aged 13 years and above

- Adjunctive or monotherapy treatment of partial seizures and generalised seizures, including tonic-clonic seizures.
- Seizures associated with Lennox-Gastaut syndrome. Lamictal is given as adjunctive therapy but may be the initial antiepileptic drug (AED) to start with in Lennox-Gastaut syndrome.

Children and adolescents aged 2 to 12 years

- Adjunctive treatment of partial seizures and generalised seizures, including tonic-clonic seizures and the seizures associated with Lennox Gastaut syndrome.
- Monotherapy of typical absence seizures.

Bipolar disorder

(Lamictal Disp/Chewable Tablets: 25MG, 50MG, 100MG, 200MG)

Adults aged 18 years and above

- Prevention of depressive episodes in patients with bipolar I disorder who experience predominantly depressive episodes.

Lamictal is not indicated for the acute treatment of manic or depressive episodes.

הרכב וחוזק:

Lamictal Dispersible/Chewable Tablets 2mg: contain 2mg Lamotrigine.
Lamictal Dispersible/Chewable Tablets 5mg: contain 5mg Lamotrigine.
Lamictal Dispersible/Chewable Tablets 25mg: contain 25mg Lamotrigine.
Lamictal Dispersible/Chewable Tablets 50mg: contain 50mg Lamotrigine.
Lamictal Dispersible/Chewable Tablets 100mg: contain 100mg Lamotrigine.
Lamictal Dispersible/Chewable Tablets 200mg: contain 200mg Lamotrigine.

4.5 Interaction with other medicinal products and other forms of interaction

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Uridine 5'-diphospho (UDP)-glucuronyl transferases (UGTs) have been identified as the enzymes responsible for metabolism of lamotrigine. Drugs that induce or inhibit glucuronidation may, therefore, affect the apparent clearance of lamotrigine. Strong or moderate inducers of the cytochrome P450 3A4 (CYP3A4) enzyme, which are also known to induce UGTs, may also enhance the metabolism of lamotrigine.

There is no evidence that lamotrigine causes clinically significant induction or inhibition of cytochrome P450 enzymes. Lamotrigine may induce its own metabolism but the effect is modest and unlikely to have significant clinical consequences.

Those drugs that have been demonstrated to have a clinically relevant significant impact on lamotrigine concentration metabolism are outlined in Table 6. Specific dosing guidance for these drugs is provided in Section 4.2. In addition, this table lists those drugs which have been shown to have little or no effect on the concentration of lamotrigine. Coadministration of such drugs would generally not be expected to result in any clinical impact. However, consideration should be given to patients whose epilepsy is especially sensitive to fluctuations in concentrations of lamotrigine.

Table 6: Effects of other medicinal products on glucuronidation the concentration of lamotrigine

Medicinal products that increase the concentration significantly inhibit glucuronidation of lamotrigine	Medicinal products that decrease the concentration significantly induce glucuronidation of lamotrigine	Medicinal products that have little or no effect on the concentration do not significantly inhibit or induce glucuronidation of lamotrigine
...	...	Paracetamol ...

*For dosing guidance (see section 4.2) plus for women taking hormonal contraceptives also see Hormonal Contraceptives in section 4.4

**Other oral contraceptive and HRT treatments have not been studied, though they may similarly affect lamotrigine pharmacokinetic parameters (see sections 4.2 and 4.4).

There is no evidence that lamotrigine causes clinically significant induction or inhibition of cytochrome P450 enzymes. Lamotrigine may induce its own metabolism but the effect is modest and unlikely to have significant clinical consequences.

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Interactions involving antiepileptic drugs

In a pooled analysis of data from three placebo-controlled clinical trials investigating adjunctive perampanel in patients with partial-onset and primary generalised tonic-clonic seizures, the highest perampanel dose evaluated (12 mg/day) increased lamotrigine clearance by less than 10%. An effect of this magnitude is not considered to be clinically relevant.

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In a study in healthy adult volunteers, 15 mg olanzapine reduced the AUC and C_{max} of lamotrigine by an average of 24% and 20%, respectively. An effect of this magnitude is not generally expected to be clinically relevant. Lamotrigine at 200 mg did not affect the pharmacokinetics of olanzapine.

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In a study of 18 adult patients with bipolar I disorder, receiving an established regimen of lamotrigine (100-400 mg/day), doses of aripiprazole were increased from 10 mg/day to a target of 30 mg/day over a 7 day period and continued once daily for a further 7 days. An average reduction of approximately 10% in C_{max} and AUC of lamotrigine was observed. **An effect of this magnitude is not expected to be of clinical consequence.**

Interactions involving other medicinal products

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In a study in healthy adult volunteers, paracetamol 1g (four times daily) reduced the plasma AUC and C_{min} of lamotrigine by an average of 20% and 25%, respectively.

העדכונים בעלון לצרכן

2. לפני השימוש בתרופה

אינטראקציות/תגובות בין תרופתיות

אם אתה לוקח, או אם לקחת לאחרונה, תרופות אחרות כולל תרופות ללא מרשם ותוספי תזונה, ספר על כך לרופא או לרוקח.

הרופא צריך לדעת אם אתה לוקח תרופות אחרות לטיפול באפילפסיה או בבעיות נפשיות וזאת כדי לוודא שאתה לוקח את המינון הנכון של למיקטל. תרופות אלה כוללות:

• ...
• **פרצטמול, המשמשת לטיפול בכאבים ובחום**

העלון לרופא והעלון לצרכן נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות:
גלקסוסמיתקליין רח' בזל 25 פתח תקוה בטלפון: 03-9297100. <https://data.health.gov.il/Drugs/index.html#!/byDrug> וניתן לקבלם מודפסים על-ידי פניה לחברת

בברכה,
שני לוי
רוקחת ממונה