



רופא/ה נכבד/ה, רוקח/ת נכבד/ה,

דצמבר 2020

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 תחת. טקסט שנמחק מסומן בקו חצייה. 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 (see section 5.1) .

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

הרכב וחוזק:

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

4.4 Special warnings and precautions for use

Skin rash

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Rash has also been reported as part a of DRESS; also known as hypersensitivity syndrome. This condition is associated with a variable pattern of systemic symptoms including fever, lymphadenopathy, facial oedema, abnormalities of the blood and₁ liver, kidney and aseptic meningitis (see section 4.8). The syndrome shows a wide spectrum of clinical severity and may, rarely, lead to disseminated intravascular coagulation and multiorgan failure. It is important to note that early manifestations of hypersensitivity (for example fever, lymphadenopathy) may be present even though rash is not evident. If such signs and symptoms are present the patient should be evaluated immediately, and Lamictal discontinued if an alternative aetiology cannot be established.

4.8 Undesirable effects

| System Organ Class | Adverse Event | Frequency |
|--|--|------------------|
| Skin and subcutaneous tissue disorders | Skin rash ^{5†§} | Very common |
| | Alopecia | Uncommon |
| | Stevens–Johnson Syndrome § | Rare |
| | Toxic epidermal necrolysis | Very rare |
| | Drug Reaction with Eosinophilia and Systemic ² Symptoms | Very rare |
| <u>Renal and urinary disorders</u> | <u>Tubulointerstitial nephritis, tubulointerstitial nephritis and uveitis syndrome</u> | Not known |

Description of selected adverse reactions

¹ Haematological abnormalities and lymphadenopathy may or may not be associated with the Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) / hypersensitivity syndrome (see Special warnings and precautions for use and Immune system disorders).

² Rash has also been reported as part of this a hypersensitivity syndrome, also known as DRESS. This condition is associated with a variable pattern of systemic symptoms including fever, lymphadenopathy, facial oedema, and abnormalities of the blood, and liver and kidney. The syndrome shows a wide spectrum of clinical severity and may, rarely, lead to disseminated intravascular coagulation and multiorgan failure. It is important to note that early manifestations of hypersensitivity (for example fever, lymphadenopathy) may be present even though rash is not evident. If such signs and symptoms are present, the patient should be evaluated immediately and Lamictal discontinued if an alternative aetiology cannot be established (see section 4.4).

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~~Rash has also been reported as part of a hypersensitivity syndrome associated with a variable pattern of systemic symptoms (see Immune system disorders).~~

העדכונים בעלון לצרכן

תופעות לוואי אחרות

תופעות לוואי אחרות התרחשו במספר קטן של משתמשים אך שכיחותן המדויקת אינה ידועה:

- ...
- דלקת של הכליה (*tubulointerstitial nephritis*), או דלקת של הכליה וגם של העין (*tubulointerstitial nephritis* - *uveitis syndrome*)

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

בברכה,

טניה רשקובן
רוקחת ממונה