



הנדון: אפיביר תמיסה לשתיה Epivir Oral Solution

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

חברת גלקסוסמיטקליין ישראל בע"מ (GSK) מבקשת להודיע על עדכון העלונים לרופא ולצרכן של התכשיר: **Epivir Oral Solution**.
העדכונים בעלונים כללו שינוי במשטר המינון של התכשיר. על כן אנו ממליצים לקרוא את העלונים בעיון.

בהודעה זו כלולים השינויים המהותיים בעלונים לרופא ולצרכן.

מרכיבים פעילים וחוזקם:

Lamivudine – 10 mg/ml

התוויה הרשומה לתכשיר בישראל:

Epivir is indicated as part of antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infected adults and children.

עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא : 

4.2 Posology and method of administration

The therapy should be initiated by a physician experienced in the management of HIV infection.

Epivir may be administered with or without food.

Epivir is also available as a tablet formulation for patients who weigh at least 14 kg (see section 4.4).

[Patients changing between lamivudine tablets and lamivudine oral solution should follow the dosing recommendations that are specific for the formulation \(see section 5.2\).](#)

For patients who are unable to swallow tablets, the tablet(s) may be crushed and added to a small amount of semi-solid food or liquid, all of which should be consumed immediately (see section 5.2).

Adults, adolescents and children (weighing at least 25 kg):

The recommended dose of Epivir is 300 mg daily. This may be administered as either 150 mg (15 ml) twice daily or 300 mg (30 ml) once daily (see section 4.4).

Children (weighing less than 25 kg):

Children from one year of age: The recommended dose is [0.5 mL/kg \(5 mg/kg\)](#) twice daily, or [1 mL/kg \(10 mg/kg\)](#) once daily ~~up to a maximum total daily dose of 300 mg (30 ml)~~ (see sections 4.4 and 4.5).

Children from three months to one year of age: The recommended dose is [0.5 mL/kg \(5 mg/kg\)](#) twice daily. If a twice daily regimen is not feasible, a once daily regimen (10 mg/kg/day) could be considered. It should be taken into account that data for the once daily regimen are very limited in this population (see sections 4.4, 5.1 and 5.2).

Children less than three months of age: The limited data available are insufficient to propose specific dosage recommendations (see section 5.2).

Patients changing from the twice daily dosing regimen to the once daily dosing regimen should take the recommended once daily dose (as described above) approximately 12 hours after the last twice daily dose, and then continue to take the recommended once daily dose (as described above) approximately every 24 hours. When changing back to a twice daily regimen, patients should take the recommended twice daily dose approximately 24 hours after the last once daily dose.

Special populations:

Older people: No specific data are available; however, special care is advised in this age group due to age-associated changes such as the decrease in renal function and alteration of haematological parameters.

Renal impairment: Lamivudine concentrations are increased in patients with moderate - severe renal impairment due to decreased clearance. The dose should therefore be adjusted (see tables).

Dosing recommendations – Adults, adolescents and children (weighing at least 25 kg):

Creatinine clearance (ml/min)	First dose	Maintenance dose
≥50	300 mg (30 ml) or 150 mg (15 ml)	300 mg (30 ml) once daily or 150 mg (15 ml) twice daily
30 to <50	150 mg (15 ml)	150 mg (15 ml) once daily
15 to <30	150 mg (15 ml)	100 mg (10 ml) once daily
5 to <15	150 mg (15 ml)	50 mg (5 ml) once daily
<5	50 mg (5 ml)	25 mg (2.5 ml) once daily

There are no data available on the use of lamivudine in children with renal impairment. Based on the assumption that creatinine clearance and lamivudine clearance are correlated similarly in children as in adults, it is recommended that the dosage in children with renal impairment be reduced according to their creatinine clearance by the same proportion as in adults. [The Epivir 10 mg/mL oral solution may be the most appropriate formulation to achieve the recommended dose in children with renal impairment aged at least 3 months and weighing less than 25kg.](#)

Dosing recommendations – Children aged at least 3 months and weighing less than 25 kg:

Creatinine clearance (ml/min)	First dose	Maintenance dose
≥50	810 mg/kg or 45 mg/kg	810 mg/kg once daily or 5 mg/kg twice daily
30 to <50	45 mg/kg	45 mg/kg once daily
15 to <30	45 mg/kg	2.63.3 mg/kg once daily
5 to <15	45 mg/kg	1.36 mg/kg once daily
<5	1.36 mg/kg	0.79 mg/kg once daily

Hepatic impairment: Data obtained in patients with moderate to severe hepatic impairment shows that lamivudine pharmacokinetics are not significantly affected by hepatic dysfunction. Based on these data, no dose adjustment is necessary in patients with moderate or severe hepatic impairment unless accompanied by renal impairment.

עדכונים מהותיים נעשו בסעיפים הבאים בעלון לצרכן :

3. כיצד תשתמש בתרופה?

ילדים מגיל 3 חודשים השוקלים פחות מ-25 ק"ג
 המינון תלוי במשקל הגוף של הילד.
 המינון המקובל בדרך כלל של אפיביר הינו **0.5 מ"ל/ק"ג (5 מ"ג / ק"ג) פעמיים ביום** (בהפרשים של כ-12 שעות בין כל מנה) או **1 מ"ל/ק"ג (10 מ"ג/ק"ג) פעם ביום עד למינון מירבי של 300 מ"ג ליום**.

מקרא לעדכונים המסומנים :
 מידע שהוסר – מסומן בקו אדום חוצה ~~XXX~~
 תוספת – כתב **כחול**
 תוספת החמרה - כתב **כחול** – מסומן בצהוב מרקר

העלונים לרופא ולצרכן נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות:
<https://data.health.gov.il/drugs/index.html#/byDrug> וניתן לקבלם מודפסים על-ידי פניה לחברת גלקסוסמיטקליין רח' בזל
 25 פתח תקוה בטלפון: 03-9297100.

בברכה,
 טניה רשקובן
 רוקחת ממונה