מאי 2020

הודעה על עדכון עלונים:

Vemlidy film coated tablets

(tenofovir alafenamide 25 mg)

רופאים ורוקחים נכבדים,

חברת גיליאד סיאנסז ישראל בע"מ מבקשת להודיעכם על עדכון בעלון לרופא ובעלון לצרכן של התכשיר בנדון.

ההתוויה הרשומה לתכשיר בישראל:

Vemlidy is indicated for the treatment of chronic hepatitis B in adults and adolescents (aged 12 years and older with body weight at least 35 kg)

השינויים מסומנים בעלון המצורף כאשר הטקסט המודגש באדום הוסף לעלון ואילו הטקסט המחוק ~~בקו חוצה~~ נגרע ממנו. הסימונים בצהוב הינם החמרות במידע הבטיחותי.

העדכונים המשמעותיים ביותר מופיעים במכתב זה, קיימים עדכונים נוספים.

העלונים לרופא ולצרכן נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות:

https://data.health.gov.il/drugs/index.html#/byDrug

כמו כן ,ניתן לקבלם מודפסים על ידי פנייה לבעל הרישום:

גיליאד סיאנסז ישראל בע"מ, רחוב החרש 4 ,ת.ד. 6090, פארק העסקים הוד השרון 4524075, ישראל.

בברכה,

מריה חורגין

רוקחת ממונה

גיליאד סיאנסז ישראל בע"מ

העדכונים המהותיים בעלון לרופא:

4.8 Undesirable effects

Summary of the safety profile

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Changes in lipid laboratory tests were observed in *Study 108* and *Study 110*. No additional adverse reactions to tenofovir alafenamide ~~Vemlidy~~ were identified from Week 96 through Week ~~120~~ 144 in the double-blind phase and in the subset of subjects receiving open-label tenofovir alafenamide ~~Vemlidy~~ treatment (see section 5.1).In an ongoing double-blind, randomized, active-controlled study (GS-US-320-4018; "*Study 4018*") in virologically suppressed subjects who switched from tenofovir disoproxil to 25 mg tenofovir alafenamide (N=243), changes in lipid laboratory tests were observed. No additional adverse reactions to tenofovir alafenamide were identified through Week 48.

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Changes in lipid laboratory tests

In a pooled analysis of *Studies 108* and *110*, median changes in fasting lipid parameters from baseline to Week 96 were observed in both treatment groups. In the tenofovir alafenamide group, decreases in median fasting total cholesterol and HDL, and increases in median fasting direct LDL and triglycerides were observed, while the tenofovir disoproxil group demonstrated median reductions in all parameters (see Table 6). In patients randomised initially to tenofovir alafenamide and switched to receive open-label tenofovir alafenamide at Week 96, the median (Q1, Q3) changes from double-blind baseline to Week 144 were as follows (mg/dL): total cholesterol was 0 (-16, 18); LDL was 8 (-6, 24); HDL was -5 (-12, 2); triglycerides were 11 (-11, 40); total cholesterol to HDL ratio was 0.3 (0.0, 0.7). In patients randomised initially to tenofovir disoproxil and switched to open-label tenofovir alafenamide at Week 96, the median (Q1, Q3) changes from double-blind baseline to Week 144 were as follows (mg/dL): total cholesterol was 1 (-17, 20); LDL was 9 (-5, 26); HDL was -8 (-15, -1); triglycerides were 14 (-10, 43); total cholesterol to HDL ratio was 0.4 (0.0, 1.0).

In the open-label phase of *Studies 108* and *110*, where patients switched to open-label tenofovir alafenamide at Week 96, lipid parameters at Week 144 in patients who remained on tenofovir alafenamide were similar to those at Week 96, whereas median increases in fasting total cholesterol, direct LDL, HDL, and triglycerides were observed in patients who switched from tenofovir disoproxil to tenofovir alafenamide at Week 96. In the open label phase, median (Q1, Q3) change from Week 96 to Week 144 in total cholesterol to HDL ratio was 0.0 (-0.2, 0.4) in patients who remained on tenofovir alafenamide and 0.2 (-0.2, 0.6) in patients who switched from tenofovir disoproxil to tenofovir alafenamide at Week 96.

In *Study 4018,* median changes in fasting lipid parameters from baseline to Week 48 were observed in both treatment groups. In the group that switched from tenofovir disoproxil to tenofovir alafenamide, increases in median fasting total cholesterol, LDL, HDL, and triglycerides were observed, while the group continuing treatment with tenofovir disoproxil demonstrated reductions in median fasting total cholesterol, HDL, and triglycerides, and a minimal median increase in LDL ($p < 0.001$ for the difference between treatment groups in all parameters). Median (Q1, Q3) change from baseline at Week 48 in total cholesterol to HDL ratio was 0.2 (-0.1, 0.5) in the tenofovir alafenamide group and 0.0 (-0.3, 0.3) in the tenofovir disoproxil group ($p < 0.001$ for the difference between treatment groups).

Metabolic parameters

Body weight and levels of blood lipids and glucose may increase during therapy.

העדכונים המהותיים בעלון לצרכן:

4. תופעות לוואי

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במהלך הטיפול ב-HBV תיתכן עלייה במשקל, ברמות השומנים ו/או גלוקוז בדם בצום. הרופא שלך יבדוק האם חלו שינויים אלה.