ספטמבר 2021

הודעה על עדכון עלונים:

Gendevra film coated tablets

(elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide fumarate)

רופאים ורוקחים נכבדים,

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

ההתוויה הרשומה לתכשיר בישראל:

Gendevra is indicated for the treatment of human immunodeficiency virus-1 (HIV-1) infection without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir as follows:

- In adults and adolescents aged from 12 years and with body weight at least 35 kg
- In children aged from 6 years and with body weight at least 25 kg for whom alternative regimens are unsuitable due to toxicities.

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

לעדכון עלונים זה מצורף מכתב לצוות הרפואי.

העדכונים המשמעותיים ביותר מופיעים במכתב זה, קיימים עדכונים מינוריים 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

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העדכונים המהותיים בעלון לרופא:

4.8 Undesirable effects

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Paediatric population

The safety profile in paediatric patients who received treatment with Gendevra was similar to that in adults.The safety of Gendevra was evaluated through 48 weeks in HIV-1 infected adolescent patients between the ages of 12 to < 18 years weighing ≥ 35 kg, who were either treatment-naïve (GS-US-292-0106, n = 50), or who were virologically-suppressed (GS-US-292-1515, n = 50), and in virologically-suppressed children between the ages of ~~8~~7 to < 12 years weighing > 25 kg (GS-US-292-0106, n = ~~23~~52).

5.1 Pharmacodynamic properties

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Paediatric population

Study GS-US-292-0106
In Study GS-US-292-0106, the efficacy, safety, and pharmacokinetics of Gendevra were evaluated in an open-label study in HIV-1-infected, treatment-naïve adolescents between the ages of 12 to < 18 years, weighing ≥ 35 kg (n = 50) in Cohort 1, and in virologically-suppressed children between the ages of ~~8~~7 to < 12 years, weighing > 25 kg (n = ~~23~~52) in Cohort 2.

Patients in Cohort 1 had a mean age of 15 years (range 12 to 17), were 44% male, 12% Asian, and 88% Black. At baseline, mean plasma HIV-1 RNA was 4.6 $\log_{10}$ copies/mL, median CD4+ cell count was 456 cells/mm^3 (range: 95 to 1,110), and median CD4+% was 23% (range: 7 to 45%). Overall, 22% had baseline plasma HIV-1 RNA > 100,000 copies/mL.

At Week 48, the virologic response rate to Gendevra in treatment-naïve HIV-1 infected adolescents was similar to response rates in studies of treatment-naïve HIV-1 infected adults. In patients treated with Gendevra, 92% (46/50) achieved HIV-1 RNA < 50 copies/mL. The mean increase from baseline in CD4+ cell count at Week 48 was 224 cells/mm^3. Three patients had virologic failure at Week 48; there was no virologic resistance detected to Gendevra.

Patients in Cohort 2 had a mean age of 10 years (range: ~~8~~7 to 11), a mean baseline weight of 32 kg (range: 26 to 58), were ~~39~~42% male, ~~13~~25% Asian, and ~~78~~71% Black. At baseline, median CD4+ cell count was ~~969~~ 926 cells/mm^3 (range: ~~603~~ 336 to ~~1,421~~1,611), and median CD4+% was ~~39~~38% (range: ~~30~~ 23 to 51%).

After switching to Gendevra, ~~100% (23/23)~~98% (51/52) of patients in Cohort 2 remained suppressed (HIV-1 RNA < 50 copies/mL) at Week 48. The mean change from baseline in CD4+ cell count and percentage at Week 48 was -~~90~~ 66 cells/mm^3 and -~~1.3~~0.6%, respectively. ~~No patient qualified for resistance analysis through Week 48.~~ One of 52 patients met the criteria for inclusion in the resistance analysis population through Week 48; no emergent resistance to Gendevra was detected through Week 48.