

אוקטובר 2021

## הודעה על עדכון עלונים:

### Gendevra film coated tablets

(elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide fumarate)

רופאים ורוקחים נכבדים,

חברת גילייד 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 המחוקק 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:

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

בברכה,

מריה חורגין

רוקחת ממונה

גילייד סיאנסז ישראל בע"מ

#### 4.5 Interaction with other medicinal products and other forms of interaction

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**Table 1: Interactions between the individual components of Gendevra and other medicinal products**

Medicinal product by therapeutic areas	Effects on medicinal product levels. Mean percent change in AUC, C <sub>max</sub> , C <sub>min</sub> <sup>1</sup>	Recommendation concerning co-administration with Gendevra
<b>GLUCOCORTICOIDS</b>		
<b>All corticosteroids excluding cutaneous products Corticosteroids</b>		
Corticosteroids primarily metabolised by CYP3A (including betamethasone, budesonide, fluticasone, mometasone, prednisone, triamcinolone).	Interaction not studied with any of the components of Gendevra.  Plasma concentrations of these medicinal products may be increased when co-administered with Gendevra, resulting in reduced serum cortisol concentrations.	Concomitant use of Gendevra and corticosteroids that are metabolised by CYP3A (e.g. fluticasone propionate or other inhaled or nasal corticosteroids) may increase the risk of development of systemic corticosteroid effects, including Cushing's syndrome and adrenal suppression.  Co-administration with CYP3A-metabolised corticosteroids is not recommended unless the potential benefit to the patient outweighs the risk, in which case patients should be monitored for systemic corticosteroid effects. Alternative corticosteroids which are less dependent on CYP3A metabolism e.g. beclomethasone for intranasal or inhalational use should be considered, particularly for long-term use.  <u>For coadministration of cutaneously-administered corticosteroids sensitive to CYP3A inhibition, refer to the prescribing information of the corticosteroid for conditions or uses that augment its systemic absorption.</u>

#### 6.1 List of excipients

##### Tablet core

Microcrystalline cellulose [\(E460\)](#)  
 Croscarmellose sodium  
 Lactose (as monohydrate)  
 Sodium lauryl sulfate  
 Magnesium stearate  
 Hydroxypropyl cellulose [\(E463\)](#)  
 Silicon dioxide [\(E551\)](#)

##### Film-coating

Polyvinyl alcohol (E1203)  
 Titanium dioxide (E171)  
 Polyethylene glycol (E1521)  
 Talc (E553b)  
 Indigo carmine aluminium lake (E132)  
 Iron oxide yellow (E172)

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#### 6.3 Shelf life

The expiry of the product is indicated on the packaging materials.

~~After first opening, use within 30 days.~~

## **2. Before taking Gendevra**

### **Other medicines and Gendevra**

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Talk to your doctor if you are taking:

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- **corticosteroids** including:
  - betamethasone, budesonide, fluticasone, mometasone, prednisone, triamcinolone.These medicines are used to treat allergies, asthma, inflammatory bowel diseases, inflammatory conditions of the skin, eyes, joints and muscles and other inflammatory conditions. These medicines are generally taken orally, inhaled, injected or applied to the skin or eye. If alternatives cannot be used, its use should only take place after medical evaluation and under close monitoring by your doctor for corticosteroid side effects.

## **5. How to store Gendevra**

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Do not use this medicine after the expiry date which is stated on the carton and bottle after {EXP}. The expiry date refers to the last day of that month. ~~After first opening, use within 30 days.~~

## **6. Additional Information**

### **What Gendevra contains**

- **In addition to the active ingredients Gendevra contains:**

*Tablet core:*

Microcrystalline cellulose (E460), croscarmellose sodium, lactose (as monohydrate), sodium lauryl sulfate, magnesium stearate, hydroxypropyl cellulose (E463), silicon dioxide (E551).

*Film-coating:*

Polyvinyl alcohol (E1203), titanium dioxide (E171), polyethylene glycol (E1521), talc (E553b), indigo carmine aluminium lake (E132), iron oxide yellow (E172).