מרץ 2025

Cerdelga™ (eliglustat) capsules

Eliglustat 84.4 mg, Hard capsules

חברת סאנופי ישראל מבקשת להודיע על עדכון העלונים לרופא ולצרכן.

ההתוויה המאושרת:

Cerdelga is indicated for the long-term treatment of adult patients with Gaucher disease type 1 (GD1), who are CYP2D6 poor metabolisers (PMs), intermediate metabolisers (IMs) or extensive metabolisers (EMs).

העדכונים העיקריים בעלונים הינם:

בעלון לרופא:

4.2 Posology and method of administration

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Mixing the content of the capsule (eliglustat powder) into food or drinks has not been studied.

4.3 Contraindications

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Cerdelga is contraindicated in patients ~~Patients~~ who are CYP2D6 ~~intermediate metabolisers (~~IMs~~)~~ or ~~extensive metabolisers (~~EMs~~)~~ taking a strong or moderate CYP2D6 inhibitor concomitantly with a strong or moderate CYP3A inhibitor, and patients who are CYP2D6 ~~poor metabolisers (~~PMs~~)~~ taking a strong CYP3A inhibitor~~. Use of Cerdelga under these conditions results in substantially elevated eliglustat plasma concentrations~~ (see section ~~4.4 and~~ 4.5).

~~Due to significantly increased eliglustat plasma concentrations,~~ Cerdelga is contraindicated in CYP2D6 ~~extensive metabolisers (~~EMs~~)~~ with severe hepatic impairment and in CYP2D6 ~~extensive metabolisers (~~EMs~~)~~ with mild or moderate hepatic impairment taking a strong or moderate CYP2D6 inhibitor (see sections 4.2 and 5.2).

4.4 Special warnings and precautions for use

~~Initiation of therapy: CYP2D6 genotyping~~
~~Before initiation of treatment with Cerdelga, patients should be genotyped for CYP2D6 to determine the CYP2D6 metaboliser status (see section 4.2, Special populations).~~

~~Drug-drug interactions~~
~~Cerdelga is contraindicated in patients who are CYP2D6 intermediate metabolisers (IMs) or extensive metabolisers (EMs) taking a strong or moderate CYP2D6 inhibitor concomitantly with~~

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~~a strong or moderate CYP3A inhibitor, and in patients who are CYP2D6 poor metabolisers (PMs) taking a strong CYP3A inhibitor (see section 4.3).~~

~~For use of eliglustat with one strong or moderate inhibitor of CYP2D6 or CYP3A, see section 4.5.~~
~~Use of eliglustat with strong CYP3A inducers substantially decreases the exposure to eliglustat, which may reduce the therapeutic effectiveness of eliglustat; therefore concomitant administration is not recommended (see section 4.5).~~

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Patients with hepatic impairment and concomitant use with other medicinal products

~~Limited data are available in CYP2D6 extensive metabolisers (EMs) with moderate hepatic impairment. Use of eliglustat in these patients is not recommended (see sections 4.2. and 5.2).~~

~~Limited or no data are available in CYP2D6 intermediate metabolisers (IMs) or poor metabolisers (PMs) with any degree of hepatic impairment. Use of eliglustat in these patients is not recommended (see sections 4.2 and 5.2).~~

Concomitant use of eliglustat with CYP2D6 or CYP3A4 inhibitors in CYP2D6 ~~extensive metabolisers (~~EMs~~)~~ with mild hepatic impairment can result in further elevation of eliglustat plasma concentrations, with the magnitude of the effect depending on the enzyme inhibited and the potency of the inhibitor. In CYP2D6 ~~extensive metabolisers (~~EMs~~)~~ with mild hepatic impairment taking a weak CYP2D6 inhibitor or strong, moderate or weak CYP3A inhibitor, a once daily dose is recommended (e.g. if a dose of 84 mg eliglustat ~~mg once~~is taken twice daily, it should be ~~considered~~ adjusted to 84 mg eliglustat once daily) (see sections 4.2 and 5.2).

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4.5 Interaction with other medicinal products and other forms of interaction

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CYP2D6 inhibitors

~~*In intermediate (in IMs) and extensive metabolisers (EMs):*~~

After repeated 84 mg twice daily doses of eliglustat in non-PMs, concomitant administration with repeated 30 mg once daily doses of paroxetine, a strong inhibitor of CYP2D6, resulted in a 7.3- and 8.9-fold increase in eliglustat C_{max} and AUC_{0-12}, respectively. ~~A dose~~Once daily dosing of eliglustat ~~84 mg once daily should be considered~~ for EMs and IMs is recommended when a strong CYP2D6 inhibitor (e.g. paroxetine, fluoxetine, quinidine, bupropion) is used concomitantly in IMs and EMs.

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4.7 Effects on ability to drive and use machines

Cerdelga may affect~~has no or negligible influence on~~ the ability to drive and use machines in patients who experience dizziness after its administration.

4.8 Undesirable effects

Summary of the safety profile

~~The overall adverse reaction profile of Cerdelga is based on 1400 patient-years of treatment exposure and pooled results from the primary analysis periods and extension periods of two pivotal Phase 3 studies (ENGAGE and ENCORE), one 8-year, long term Phase 2 study (Study 304) and one supporting Phase 3b study (EDGE). In these four studies a total of 393 patients between the ages of 16-75 years received eliglustat for a median duration of 3.5 years (up to 9.3 years).~~

The most frequently reported adverse reaction with eliglustat ~~Cerdelga~~ is dyspepsia, in approximately 6% of the clinical trial patients.

Tabulated list of adverse reactions

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בעלון לצרכן:

2. לפני השימוש בתרופה

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נהיגה ושימוש במכונות

~~ל~~סרדלגה ~~יש השפעה זניחה או חוסר השפעה~~עלולה להשפיע על יכולת הנהיגה או הפעלה של מכונות במטופלים שחווים סחרחורת לאחר נטילתה.

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3. כיצד תשתמש בתרופה

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ערבוב תכולת הכמוסה (אבקת אליגלוסטאט) עם מזון או משקה לא נבדק.

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4. תופעות לוואי

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תופעות לוואי שכיחות (common) תופעות שמופיעות ב- 1-10 משתמשים מתוך 100:

- .....
- כאב בקיבה (בבטן העליונה)
- ~~בחילה~~
- ~~שלשול~~
- ~~עצירות~~
- ~~כאב בטן~~
- שלשול
- בחילה
- עצירות

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- כאב בטן
- .....

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העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלם מודפסים על ידי פנייה לבעל הרישום- סאנופי-אוונטיס ישראל בע"מ, Greenwork Park, מתחם העסקים בקיבוץ יקום, בניין E (קומה 1), 6097600, יקום או בטלפון: 09-8633081.

להלן הקישור לאתר משרד הבריאות:
https://israeldrugs.health.gov.il/#!/byDrug

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