מאי 2020

רופא/ה רוקח/ת נכבד/ה,

חברת סאנופי-אוונטיס ישראל בע"מ מבקשת להודיע על עדכון **העלון לצרכן במתכונת עלון לרופא** של התכשיר:

MYOZYME, *powder for concentrate for solution for infusion.*

החומר פעיל:

alglucosidase alfa

ההתוויה המאושרת:

Myozyme is indicated for long-term enzyme replacement therapy (ERT) in patients with a confirmed diagnosis of Pompe disease (acid alpha-glucosidase deficiency).
The benefits of Myozyme in patients with late-onset Pompe disease have not been established.

מפורטים להלן רק תתי הסעיפים בהם נעשו העדכונים העיקריים בעלונים:

4.4 Special warnings and precautions for use

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Immunomodulation
Immunogenicity data from clinical trials and published literature in CRIM-negative infantile-onset patients (IOPD) suggests that the administration of immune tolerance induction (ITI) regimen given to alglucosidase alfa naive patients (prophylactic ITI) may be effective in preventing or reducing the development of High Sustained Antibody Titer (HSAT) against alglucosidase alfa. Data from a small number of patients with HSAT, with or without inhibitory activity, showed limited ITI treatment effect. Better treatment responses were observed in younger patients with less advanced disease who received prophylactic ITI before development of HSAT, which suggests that early initiation of ITI can result in improved clinical outcomes. ITI regimens may need to be tailored to individual patient needs (see section 5.1).

Patients with Pompe disease are at increased risk of respiratory infections due to the progressive effects of the disease on the respiratory muscles. Patients with Pompe disease treated with immunosuppressive agents maybe at further increased risk of developing severe infections and vigilance is recommended.Fatal and life-threatening respiratory infections have been observed in some of these patients.
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4.8 Undesirable effects
Tabulated list of adverse reactions
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System Organ Class	Frequency	Adverse reaction (Preferred Term Level)		Additional adverse reactions[4]
		Infantile-onset Pompe disease[1]	Late-onset Pompe disease[2]	Infantile- and Late-onset Pompe disease
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General disorders and administration site conditions	not known			Chest pain Face edema Feeling hot Pyrexia Chills Chest discomfort Irritability Peripheral coldness Infusion site pain Infusion site reaction Infusion site swelling Infusion site induration Infusion site extravasation

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5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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IOPD Immune Tolerance Induction

Use of ITI and alglucosidase alfa has been evaluated in 1 clinical trial and a retrospective chart review of patients naïve to ERT at the initiation of treatment and 1 clinical trial of patients already receiving alglucosidase alfa at time of initiating ITI.

A retrospective chart review at Duke Center identified 21 CRIM-negative IOPD patients of which 19 patients were ERT naïve at the time of ITI initiation. Of the 21 patients, 16 survived through the end of this study, with a median time from ERT initiation to last assessment of 44.6 months (range: 5.7 to 105.47); 5 patients died due to respiratory failure and disease progression, all of whom were ERT-naïve at the start of ERT+ITI treatment. Younger patients diagnosed and treated early and who received ITI concomitantly to ERT initiation had a trend towards better survival rate than patients treated with similar regimen at a later age. The study data demonstrated that prophylactic ITI prevents or reduces the occurrence of antibodies against alglucosidase alfa over time, which may maintain clinical benefit of ERT and improve survival in CRIM-negative IOPD patients.

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השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה.

העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות . בנוסף ניתן לקבלם מודפסים על ידי פנייה לבעל הרישום, סאנופי-אוונטיס ישראל בע"מ, רח' בני גאון 10 נתניה או בטלפון : 09-8633700 .להלן הקישור לאתר משרד הבריאות :
https://data.health.gov.il/drugs/index.html#!/byDrug

בברכה,

צליל גנר להב

רוקחת ממונה

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