



ינואר 2023

Myozyme (Powder for Concentrate for Infusion)

חומר פעיל:

Alglucosidase alfa 50 mg/vial

ההתוויה המאושרת:

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

חברת סאנופי אוונטיס מבקשת להודיע על עדכון העלון לצרכן במתכונת עלון לרופא.

העדכונים העיקריים הינם:

4.8. Undesirable effects

.....

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
.....
Cardiac disorders
	not known		 Palpitations
.....
General disorders and administration site conditions
	not known		 Asthenia Malaise Feeling cold

	not known		 Blood pressure decreased



4.9 Overdose

~~There is no experience with overdose of alglucosidase alfa.~~ In clinical studies doses up to 40 mg/kg body weight were used. IARs are more likely to occur with higher dose or infusion rates than recommended (see section 4.4).

Symptoms and signs

IARs have been reported, which included:

- cyanosis, tachycardia, palpitations
- hypoxia, dyspnoea, cough
- dizziness, headache, dysgeusia
- hypertension, flushing
- tongue oedema, vomiting, diarrhoea, nausea
- chest pain, chest discomfort, throat tightness, pyrexia, chills, feeling cold, infusion site erythema,
- myalgia
- erythema

Management

~~In the event of overdose, the infusion rate should be reduced, or the infusion temporarily interrupted. There is no known specific antidote for alglucosidase alfa overdose. The patient should be monitored for any signs or symptoms of adverse reactions and, if required, administered appropriate symptomatic treatment immediately.~~

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס 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://israeldrugs.health.gov.il/#!/byDrug>

בברכה,

חברת סאנופי אוונטיס ישראל בע"מ