



נובמבר 2022

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:

4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name of the administered product should be clearly recorded. It is recommended to record the batch number as well.

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4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. Because dizziness, **somnolence, tremor and hypotension** has have been reported as an infusion associated reaction, this may affect the ability to drive and use machines on the day of the infusion.

4.8 Undesirable effects

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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 |
| | | | | |
| Nervous system disorders | | | | |
| | not known | | | Tremor Headache Somnolence |



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|--|-----------|-------|-------|--|
| Respiratory, thoracic and mediastinal disorders | | | | |
| | | | | |
| | not known | | | Respiratory arrest Apnea Respiratory distress Bronchospasm Wheezing Pharyngeal oedema Dyspnoea Tachypnoea Throat tightness Throat irritation Stridor Cough Hypoxia |
| Gastrointestinal disorders | | | | |
| | | | | |
| | not known | | | Abdominal pain Retching Dyspepsia Dysphagia |
| Skin and subcutaneous tissue disorders | | | | |
| | | | | |
| | not known | | | Periorbital edema Livedo reticularis Lacrimation increased Rash Erythema Hyperhidrosis Palmar erythema Transient skin discoloration Blister |
| General disorders and administration site conditions | | | | |
| | | | | |
| | not known | | | Chest pain Face edema Feeling hot Pyrexia Chills Chest discomfort Irritability |



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|--|--|--|--|--|
| | | | | Peripheral coldness Infusion site pain Infusion site reaction Infusion site swelling Infusion site induration Infusion site extravasation Infusion site erythema Infusion site urticaria Infusion site pruritus |
|--|--|--|--|--|

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס על ידי פנייה לבעל הרישום - סאנופי-אונטיס 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 אונטיס ישראל בע"מ