אוגוסט 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:

4.6 Fertility, pregnancy and lactation

Pregnancy

There is limited~~are no~~ data from the use of alglucosidase alfa in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3). ~~The potential risk for humans is unknown.~~ Myozyme should not be used during pregnancy unless the clinical condition of the woman requires treatment with alglucosidase alfa~~clearly necessary~~.

Breast-feeding

~~——~~Limited data suggest that ~~Alglucosidase~~ alglucosidase alfa ~~may be~~is excreted in breast milk in very low concentrations. No clinical effect is expected in a breastfed infant due to low breast milk transfer and poor bioavailability. Breastfeeding during treatment with Myozyme may therefore be considered. As a precautionary measure, breastfeeding interruption for the first 24 hours after treatment may be considered.~~Because there are no data available on effects in neonates exposed to alglucosidase alfa via breast milk, it is recommended to stop breast-feeding when Myozyme is used.~~

Fertility

There is too limited~~are no~~ clinical data on the effects of alglucosidase alfa on fertility to evaluate its impact. Preclinical data did not reveal any significant adverse findings (see section 5.3).

4.9 Overdose

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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.

5.3. Preclinical safety data

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טל': 09-8633700 פקס: 09-8851444

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Administration of 40 mg/kg Myozyme intravenously once every other day in mice with coadministration of diphenhydramine during the period of organogenesis through lactation produced an increase in mortality of offspring during the lactation period. There were no other effects on any parameter evaluated including clinical observations or body weight gain in F1 generation pups. Furthermore, no effect on sexual maturation, learning or memory, or the ability to produce another generation occurred for the F1 generation mice.

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

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