

NAGLAZYME-נגלזיים
CONCENTRATE FOR SOLUTION FOR INFUSION

הרכב:

Each ml of solution contains 1 mg galsulfase. One vial of 5 ml contains 5 mg galsulfase.

התוויה מאושרת:

Naglazyme is indicated for long-term enzyme replacement therapy in patients with a confirmed diagnosis of MPSVI (N-acetylgalactosamine 4 sulfatase deficiency Maroteaux-Lamy syndrome).

להלן העדכונים בעלון לרופא:

4.4 Special warnings and precautions for use

[.....]

~~This medicinal product contains 0.8 mmol (18.4 mg) sodium per vial and is administered in sodium chloride 9 mg/ml solution for injection (see section 6.6). To be taken into consideration by patients on a controlled sodium diet.~~

Spinal or cervical cord compression

Spinal/cervical cord compression (SCC) with resultant myelopathy is a known and serious complication that can be due to MPS VI. There have been post-marketing reports of patients treated with Naglazyme who experienced the onset or worsening of SCC requiring decompression surgery. Patients should be monitored for signs and symptoms of spinal/cervical cord compression (including back pain, paralysis of limbs below the level of compression, urinary and faecal incontinence) and given appropriate clinical care.

Risk of Acute Cardio-respiratory Failure

Caution should be exercised when administering Naglazyme to patients susceptible to fluid volume overload; such as in patients weighing 20 kg or less, patients with acute underlying respiratory illness, or patients with compromised cardiac and/or respiratory function, because congestive heart failure may occur. Appropriate medical support and monitoring measures should be readily available during Naglazyme infusion, and some patients may require prolonged observation times that should be based on the individual needs of the patient (see section 4.2).

Immune-mediated Reactions

Type III immune complex-mediated reactions including membranous glomerulonephritis have been observed with Naglazyme. If immune-mediated reactions occur, discontinuation of the administration of Naglazyme should be considered, and appropriate medical treatment initiated. The risks and benefits of



re-administering Naglazyme following an immune-mediated reaction should be considered (see section 4.2).

Sodium restricted diet

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העלון לרופא נמצא בקישור וכן מפורסם במאגר התרופות באתר משרד הבריאות וניתן לקבלו מודפס על ידי פניה לבעל הרישום.

בברכה,

שרון עמיר
רוקחת ממונה

