

רופא/ה, רוקח/ת נכבדים,

הריני להודיעכם כי העלון של התכשיר עודכן:

Vimizim
וימיזים
concentrate for solution for infusion

QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each ml of solution contains 1 mg elosulfase alfa*. Each vial of 5 ml contains 5 mg elosulfase alfa.

*Elosulfase alfa is a recombinant form of human N-acetylgalactosamine-6-sulfatase (rhGALNS) and is produced in Chinese Hamster Ovary cell culture by recombinant DNA technology.

התוויה מאושרת-

Vimizim is indicated for the treatment of mucopolysaccharidosis, type IVA (Morquio A Syndrome, MPS IVA) in patients of all ages.

נעשה עדכון בעלון לרופא בסעיף הבא:

4.4 Special warnings and precautions for use

Sodium restricted diet

This medicinal product contains 8 mg sodium per vial, equivalent to 0.4% of the WHO recommended maximum daily intake of 2 g sodium for an adult, and is administered in sodium chloride 9 mg/ml (0.9%) solution for infusion (see section 6.6).

Sorbitol

This medicinal product contains 100 mg sorbitol in each vial which is equivalent to 40 mg/kg. Patients with hereditary fructose intolerance (HFI) must not be given this medicinal product unless strictly necessary.

Babies and young children (below 2 years of age) may not yet be diagnosed with hereditary fructose intolerance (HFI). Medicinal products (containing sorbitol/fructose) given intravenously may be life-threatening. The treatment benefit to the child compared to the associated risks must be fully evaluated prior to treatment.

A detailed history with regard to HFI symptoms has to be taken for each patient prior to being given this medicinal product.

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

בברכה,



מגר' חיה שליו
רוקחת ממונה

