הודעה על החמרה (מידע בטיחות) בעלון לרופא (מעודכן 05.2013)

תאריך 29/10/17_____

שם תכשיר באנגלית Fabrazyme 5mg and Fabrazyme 35mg

מספר רישום 131-99-31079-00 and 124-94-30313-00

שם בעל הרישום __סאנופי-אוונטיס ישראל _____

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
טקסט חדש	**טקסט נוכחי**	**פרק בעלון**
מידע שהתווסף ומהווה החמרה מסומן בצהוב , מידע מלא של סעיף זה ניתן למצוא בעלון המלא): Fabrazyme is indicated in adults, children and adolescents aged 8 years and older		**4.1 Therapeutic indications**
מידע שהתווסף ומהווה החמרה מסומן בצהוב , מידע מלא של סעיף זה ניתן למצוא בעלון המלא): Paediatric population The safety and efficacy of Fabrazyme in children aged 0 to7 years have not yet been established. Currently available data are described in sections 5.1 and 5.2 but no recommendation on posology can be made in children aged 5 to 7 years. No data are available in children 0 to 4 years		**4.2 Posology and method of administration**
מידע שהתווסף ומהווה החמרה מסומן בצהוב , מידע מלא של סעיף זה ניתן למצוא בעלון המלא): Limited information from clinical trials suggests that the safety profile of Fabrazyme treatment in paediatric patients ages 5-7, treated with either 0.5 mg/kg every 2 weeks or 1.0 mg/kg every 4 weeks is similar to that of patients (above the age of 7) treated at 1.0 mg/kg every 2 weeks.		**4.8 Undesirable effects**
In an additional 5-year open-label paediatric study, 31 male patients aged 5 to 18 years were randomized prior to the onset of clinical symptoms involving major organs and treated with two lower dose regimens of agalsidase beta, 0.5 mg/kg every 2 weeks or 1.0 mg/kg every 4 weeks. Results were similar between the two treatment groups. Superficial skin capillary endothelium GL-3 scores were reduced to zero or maintained at zero at all time points post-baseline upon treatment in 19/27 patients completing the study without a dose increase. Both baseline and 5-year kidney biopsies were obtained in a subset of 6 patients: in all, kidney capillary endothelium GL-3 scores were reduced to zero but highly variable effects were observed in podocyte GL-3, with a reduction		**5.1 Pharmacodynamic properties**

in 3 patients. Ten (10) patients met per protocol dose increase criteria, two (2) had a dose increase to the recommended dose of 1.0 mg/kg every 2 weeks.		
In another study with 30 paediatric patients with available pharmacokinetics data, aged 5 to 18 years, treated with two lower dose regimens of 0.5 mg/kg every 2 weeks and 1.0 mg/kg every 4 weeks, mean CL was 4.6 and 2.3 ml/min/kg, respectively, mean Vss was 0.27 and 0.22 l/kg, respectively, and mean elimination half-life was 88 and 107 minutes, respectively. After IgG seroconversion, there was no apparent change in CL (+24% and +6%, resp.), while Vss was 1.8 and 2.2 fold higher, with the net effect being a small decrease in C_{max} (up to -34% and -11%, resp.) and no change in AUC (-19% and -6%, resp.).		**5.2 Pharmacokinetic properties**