אושר – 2.16

תאריך: 22.02.2016

שם תכשיר באנגלית ומספר הרישום ELAPRASE

138 94 31772 00

שם בעל הרישום: מדיסון פארמה בע"מ

טופס זה מיועד לפרוט ההחמרות בלבד !

הודעה על החמרה (מידע בטיחות) בעלון לרופא

ההחמרות המבוקשות		
טקסט חדש	**טקסט נוכחי**	**פרק בעלון**
5.1 Pharmacodynamic properties Among all patients, statistically significant mean increases from treatment baseline (TKT024 baseline for TKT024 idursulfase patients and Week 53 baseline for TKT024 placebo patients) were seen in the distance walked 6MWT at the majority of time points tested, with significant mean and percent increases ranging from 13.7m to 41.5m ~~and from 6.4% to 11.7%~~ (maximum at Month 20) and from 6.4% to 13.3% (maximum at Month 24) respectively. At most time points tested, patients who were from the original TKT024 weekly treatment group improved their walking distance to a greater extent that patients in the other 2 treatment groups. Statistically significant increases from treatment baseline in absolute FVC volume were seen at most visits for all treatment groups combined and for each of the prior TKT024 treatment groups. Mean changes from 0.07 l to 0.31 l and percent ranged from 6.3% to 25.5~~1~~% (maximum at Month 30). The mean and percent changes from treatment baseline were greatest in the group of patients from the TKT024 study who had received the weekly dosing, across all time points.	**5.1 Pharmacodynamic properties** Among all patients, statistically significant mean increases from treatment baseline (TKT024 baseline for TKT024 idursulfase patients and Week 53 baseline for TKT024 placebo patients) were seen in the distance walked 6MWT at the majority of time points tested, with significant mean and percent increases ranging from 13.7m to 41.5m and from 6.4% to 11.7% (maximum at Month 20). At most time points tested, patients who were from the original TKT024 weekly treatment group improved their walking distance to a greater extent that patients in the other 2 treatment groups. Among all patients, mean % predicted FVC was significantly increased at Month 16, although by Month 36, it was similar to the baseline. Patients with the most severe pulmonary impairment at baseline (as measured by % predicted FVC) tended to show the least improvement. Statistically significant increases from treatment baseline in absolute FVC volume were seen at most visits for each of the prior TKT024 treatment groups. Mean changes from 0.07 l to 0.31 l and percent ranged from 6.3% to 25.1% (maximum at Month 30). The mean and percent changes from treatment baseline were greatest in the group of patients from the TKT024 study who had received the weekly dosing, across all time points.	**5.PHARMACOLOGICAL PROPERTIES** **5.1 Pharmacodynamic properties**
6.6 Special precautions for disposal and other handling Each vial of Elaprase is intended for	**6.6 Special precautions for disposal and other handling**	**6.6 Special precautions for disposal and**

single use only and contains 6 mg of idursulfase in 3 ml of solution. Elaprase is for intravenous infusion and must be diluted in sodium chloride 9 mg/ml (0.9%) solution for infusion prior to use. It is recommended to deliver the total volume of infusion using a 0.2 µm in line filter. Elaprase should not be infused with other products in the infusion tubing. Determine the number of vials to be diluted based on the individual patient's weight and the recommended dose of 0.5 mg/kg. - Do not use if the solution in the vials is discoloured or if particulate matter is present. Do not shake. - Withdraw the calculated volume of Elaprase from the appropriate number of vials. - Dilute the total volume required of Elaprase in 100 ml of 9 mg/ml (0.9%) sodium chloride solution for infusion. Care must be taken to ensure the sterility of the prepared solutions since Elaprase does not contain any preservative or bacteriostatic agent; aseptic technique must be observed. Once diluted, the solution should be mixed gently, but not shaken. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.	Each vial of Elaprase is intended for single use only and contains 6 mg of idursulfase in 3 ml of solution. Elaprase is for intravenous infusion and must be diluted in sodium chloride 9 mg/ml (0.9%) solution for infusion prior to use. - Determine the number of vials to be diluted based on the individual patient's weight and the recommended dose of 0.5 mg/kg. - Do not use if the solution in the vials is discoloured or if particulate matter is present. Do not shake. - Withdraw the calculated volume of Elaprase from the appropriate number of vials. - Dilute the total volume required of Elaprase in 100 ml of 9 mg/ml (0.9%) sodium chloride solution for infusion. Care must be taken to ensure the sterility of the prepared solutions since Elaprase does not contain any preservative or bacteriostatic agent; aseptic technique must be observed. Once diluted, the solution should be mixed gently, but not shaken. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.	**other handling**

מצ"ב העלון, שבו מסומנות ההחמרות המבוקשות על רקע צהוב.
שינויים שאינם בגדר החמרות סומנו (בעלון) בצבע ירוק. יש לסמן רק תוכן מהותי ולא שינויים במיקום הטקסט.