הודעה על החמרה (מידע בטיחות)

תאריך: באוגוסט 2014
שם תכשיר באנגלית: REMODULIN SOLUTION FOR INJECTION 2.5 / 5 MG/ML
מספר רישום: 1265730563, 1265630562,
שם בעל הרישום: מעבדות רפא בע"מ

השינויים בעלון מסומנים בצבע: צהוב=הוספה, ~~ירוק~~=מחיקה.

בעלון לרופא

טקסט חדש	טקסט נוכחי	פרק בעלון
…~~There is little experience with doses >40 ng/kg/min~~ …	…There is little experience with doses >40 ng/kg/min...	**Dosage and Administration: 2.3 Dosage Adjustments**
…Infusion sets with an in-line 0.22 or 0.2 micron pore size filter should be used…	--	**2.6 Administration: Intravenous Infusion**
…Administration of IV Remodulin with a high pH glycine has been associated with a lower incidence of BSIs when compared to neutral diluents (sterile water, 0.9% sodium chloride) when used along with catheter care guidelines…	…	**5. Warnings and precautions: 5.1 Risks Attributable to the Drug Delivery System**
…The safety of Remodulin was also studied in a long-term, open-label extension study in which 860 patients were dosed for a mean duration of 1.6 years, with a maximum exposure of 4.6 years. Twenty-nine (29%) percent achieved a dose of at least 40 ng/kg/min (max: 290 ng/kg/min). The safety profile during this chronic dosing study was similar to that observed in the 12-week placebo controlled study except for the following suspected adverse drug reactions (occurring in at least 3% of patients): anorexia, vomiting, infusion site infection, asthenia, and abdominal pain…	--	**6. Adverse Reactions 6.1 Clinical Trials Experience** **Adverse Events during Chronic Dosing**
…Patients receiving intravenous infusion should use an infusion set with an in-line filter…	--	**17. Patient Counseling Information**

בעלון לצרכן – נשלח המלצה עבור עלון לצרכן