הודעה על החמרה (מידע בטיחות) בעלון לרופא

תאריך: 13.3.17

שם תכשיר באנגלית ומספר הרישום: DIPEPTIVEN (136 14 31269 01-02)

שם בעל הרישום: CURE MEDICAL & TECHNICAL SUPPLY

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות

פרק בעלון	טקסט חדש	טקסט נוכחי
Special warnings and precautions for use	For a safe administration the maximum dose of Dipeptiven should not exceed 2.0 ml (corresponding to 0.4 g N(2)-L-alanyl-L-glutamine) per kg body weight per day (see section 4.2, 4.9 and 5.1). Dipeptiven should only be used as part of clinical nutrition, and its dosage is limited by the amount of protein/amino acids provided by nutrition (see section 4.2). Whenever the clinical condition does not allow nutrition (e.g., circulatory shock, hypoxia, severe metabolic acidosis) Dipeptiven should not be administered. Oral/enteral intake of glutamine-supplemented formulas in combination with parenteral nutrition should be taken into consideration for calculation of the prescribed dose of Dipeptiven. It is advisable to regularly monitor liver function parameters in patients with compensated hepatic insufficiency. As there is currently insufficient data on administration of Dipeptiven to pregnant women, nursing mothers and children, administration of the preparation in these patient groups is not recommended.	It is advisable to regularly monitor liver function parameters in patients with compensated hepatic insufficiency. As there is currently insufficient data on administration of Dipeptiven to pregnant women, nursing mothers and children, administration of the preparation in these patient groups is not recommended. Serum electrolytes, serum osmolarity, water balance, acid-base status as well as liver function tests (alkaline phospatase, ALT, AST), possible symptoms of hyperammonaemia should be controlled. The enzymes alkaline phosphatase, GPT, GOT, bilirubin level and the acid-base status should be monitored. The choice of a peripheral or central vein depends on the final osmolarity of the mixture. The general accepted limit for peripheral infusion is about 800 mosmol/l but it varies considerably with the age and general condition of the patient and the characteristics of the peripheral veins. Experience with the use of Dipeptiven for longer periods than nine days is limited.

	Serum electrolytes, serum osmolarity, water balance, acid-base status as well as liver function tests (alkaline phospatase, ALT, AST), and possible symptoms of hyperammonaemia should be controlled. The enzymes alkaline phosphatase, GPT, GOT, bilirubin level and the acid-base status should be monitored. The choice of a peripheral or central vein depends on the final osmolarity of the mixture. The generally accepted limit for peripheral infusion is about 800 mosmol/l but it varies considerably with the age and general condition of the patient and the characteristics of the peripheral veins. Experience with the use of Dipeptiven for longer periods than nine days is limited.	
As with other infusion solutions, chills, nausea and vomiting can occur when the infusion rate of Dipeptiven is exceeded. Infusion shall be stopped immediately in this case.	As with other infusion solutions, chills, nausea and vomiting can occur when the infusion rate of Dipeptiven is exceeded. Infusion shall be stopped immediately in this case. Experience from a study in critically ill patients with at least two organ failures at admission, receiving the maximum approved daily intravenous infusion of Dipeptiven (0.5 g alanyl-glutamine/kg/day) together with a high dose of enteral glutamine (30 g) provided as a mixture of alanyl-glutamine and glycyl-glutamine and without appropriate clinical nutrition, has shown an increase in serious side effects.	***Overdose***