הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך: 29-Sep-2016

שם התכשיר באנגלית ומספר הרישום:

Konakion MM Paediatric 2mg/0.2ml (105.47.28944.00)

שם בעל הרישום: Roche Pharmaceuticals (Israel) Ltd

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות

טקסט חדש	טקסט נוכחי	פרק בעלון
At the time of use, the mixed-micelle ampoule solution must be clear in appearance. Parenteral administration may be associated with an increased risk of kernicterus in premature infants weighing less than 2.5 kg.	Parenteral administration may be associated with an increased risk of kernicterus in premature infants weighing less than 2.5 kg.	**Precautions**
The half-life of vitamin K_1 in plasma is about 70 hours. Vitamin K_1 is excreted in the bile and urine as glucuronide and sulphate conjugates.	The half-life of vitamin K_1 in plasma is about 1.5 to 3 hours. Vitamin K_1 is excreted in the bile and urine as glucuronide and sulphate conjugates.	**Pharmacokinetics/ Elimination**
Infants with cholestatic liver disease […] Median serum vitamin K_1 concentrations were similar in the oral and intravenous groups at baseline (0.92 vs. 1.15 ng/ml) rising to approximately 100 times higher concentrations six hours after intravenous K_1 compared to oral administration (139 ng/ml vs. 1.4 ng/ml). […]	Infants with cholestatic liver disease […] Median serum vitamin K_1 concentrations were similar in the oral and intravenous groups at baseline (0.92 vs. 1.15 ng/ml) rising to approximately 10 times higher concentrations six hours after intravenous K_1 compared to oral administration (139 ng/ml vs. 1.4 ng/ml). […]	**Pharmacokinetic of oral vs. iv mixed micellar vitamin K prophylaxis in special populations**

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