

מרץ 2024

רופא/ה נכבד/ה

,הוקח/ת נכבד/ה,

ברצוננו להביא לידיעתכם את העדכונים בעלון לרופא של התכשיר:

**Hepagam B™ (140 62 31748 00)**  
SOLUTION FOR INJECTION

המאושר להתוויה הבאה:

Prevention of hepatitis B recurrence following liver transplantation: Hepagam B is indicated for the prevention of hepatitis B recurrence following liver transplantation in HBsAg-positive liver transplant patients. Hepagam B should be administered intravenously for this indication. Postexposure prophylaxis : Hepagam B is indicated for the treatment of acute exposure to blood containing HBsAg perinatal exposure of infants born to HBsAg-positive mothers sexual exposure to HBsAg-positive persons and household exposure to persons with acute HBV infection in the following settings: Acute exposure to blood containing HBsAg Following either parenteral exposure (needlestick bite sharps) direct mucous membrane contact (accidental splash) or oral ingestion (pipetting accident) involving HBsAg - positive materials such as blood plasma or serum. Perinatal exposure of infants born to HBsAg-positive mothers Infants born to mothers positive for HBsAg with or without HBeAg. Perinatal exposure of infants born to HBsAg-positive persons Sexual partners of HBsAg-positive persons. Household exposure to persons with acute HBV infection Infants less than 12 months old whose mother or primary caregiver is positive for HBsAg. Other household contacts with an identifiable blood exposure to the index patient. Hepagam B is indicated for intramuscular use only for these post-exposure prophylaxis indications.

להלן עיקרי השינויים בעלון התכשיר:

**7. MANUFACTURER**

~~Emergent Biosolution Canada Inc.~~ **KI BioPharma LLC, Winnipeg** ~~Manitoba~~ **Wilmington, New Castle County,**  
~~Canada~~ **Delaware, USA.**

לשאר העדכונים בעלון יש לעיין בעלון המלא שנשלח לפרסום במאגר התרופות באתר משה"ב. ניתן לקבלו מודפס על ידי פנייה לבעל הרישום, צמל ביו פארמה בע"מ טלפון: 073-7151111.

בברכה,  
צמל ביו פארמה בע"מ