יוני 2024

רופא/ה נכבד/ה

רוקח/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 HBsAg.
Perinatal exposure of infants born to HBsAg-positive persons

Sexual Exposure 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 (מידע בטיחותי שנוסף לעלון):

Hematologic

IGIV products can contain blood group antibodies which may act as haemolysins and induce in vivo coating of red blood cells (RBC) with immunoglobulin, causing a positive direct antiglobulin reaction (Coombs' test) and, rarely, haemolysis. Haemolytic anaemia can develop subsequent to IGIV therapy due to enhanced RBC sequestration. IGIV recipients should be monitored for clinical signs and symptoms of haemolysis (see WARNINGS AND PRECAUTIONS: Monitoring and Laboratory Tests).

Neurologic

Neurologic Aseptic Meningitis Syndrome (AMS) has been reported to occur in association with IGIV treatment. The syndrome usually begins within several hours to 2 days following IGIV treatment. Cerebrospinal fluid (CSF) studies are frequently positive with pleocytosis up to several thousand cells per mm3, predominantly from the granulocytic series, and elevated protein levels up to several hundred mg/dL. AMS may occur more frequently in association with high-dose (2 g/kg) IGIV treatment. Patients exhibiting such signs and symptoms should receive a thorough neurological examination, including CSF studies, to rule out other causes of meningitis. Discontinuation of IGIV treatment has resulted in remission of AMS within several days without sequelae.

Respiratory

In patients receiving IGIV, there have been some reports of acute non-cardiogenic pulmonary oedema [Transfusion-related acute lung injury (TRALI)]. TRALI is characterised by severe hypoxia, dyspnoea, tachypnoea, cyanosis, fever and hypotension. Symptoms of TRALI typically develop during or within 6 hours after a transfusion, often within 1–2 hours. Therefore, IGIV recipients must be monitored for and IGIV infusion must be immediately stopped in case of pulmonary adverse reactions. TRALI is a potentially life-threatening condition requiring immediate intensive-care-unit management.

8. ADVERSE REACTIONS

In clinical trial HB-009, with 11 liver transplant patients who received total of 194 infusions of HepaGam B, 212 adverse events were reported. Only five adverse events were deemed related to study drug, all affecting a single participant. These five AEs were hypertension, dyspnea, pyrexia, infusion related reaction, and increased respiratory rate. All were deemed mild in intensity and consistent with a faster than usual infusion rate. A total of 25 serious adverse events were reported by six participants. None of the serious adverse events were deemed related to study drug.

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