

חברת קמהדע מבקשת להודיע על עידכון עלון לרופא עבור התכשיר:

HEPATECT® CP ; הפטקט CP
Solution for Infusion

מרכיבים פעילים בהתאם לרישיון:

Protein Immunoglobulin 50mg/ml

התוויה:

A. Prophylaxis against hepatitis B in adults and children over two years of age who have not been vaccinated against hepatitis B (including persons whose vaccination is incomplete or missing) who are at risk of infection with hepatitis B by accidental contact with hepatitis B virus containing material following

- percutaneous exposure (e.g., accidental needle stick)
- direct mucous membrane contact

When the administration of an intramuscular hepatitis B immunoglobulin is not possible.

The immunoglobulin should be administered in association with hepatitis B vaccine.

B. Prophylaxis against re-infection of a transplanted liver in patients who carry the surface antigen of the hepatitis B virus

C. Immunoprophylaxis of hepatitis B in the newborn of a hepatitis B virus carrier-mother.

מהות השינויים: עידכון עלון לרופא.

בהודעה זו מצוינים השינויים המהווים החמרה (הודגשו בצהוב; טקסט שנמחק סומן ע"י קו חוצה). בעלון שינויים נוספים שאינם החמרה.

4.8 Undesirable effects

~~There are no robust data on the frequency of undesirable effects from clinical trials.~~

Summary of the safety profile

Most adverse drug reactions (ADRs) were mild to moderate in nature. In isolated cases human normal immunoglobulins may cause an anaphylactic shock.

Tabulated list of adverse reactions:

The table presented below is according to the MedDRA system organ classification (SOC and Preferred Term Level). Frequencies have been evaluated according to the following convention:

Very common ($\geq 1/10$); Common ($\geq 1/100$ to $< 1/10$); Uncommon ($\geq 1/1,000$ to $< 1/100$); Rare ($\geq 1/10,000$ to $< 1/1,000$); Very rare ($< 1/10,000$); Not known (cannot be estimated from the available data).

The following ADRs are cumulated from clinical trials and post-marketing reporting:

MedDRA Standard System Organ Class	Undesirable effects	Frequency
Immune system disorders	Hypersensitivity	Rare
	anaphylactic shock	Very rare
Nervous system disorders	Headache	Rare

Cardiac disorders	Tachycardia	Rare
Vascular disorders	Hypotension	Rare
Gastrointestinal disorders	Nausea, vomiting	Rare
Skin and subcutaneous tissue disorders	Skin reaction, erythema, itching, pruritus	Rare
Musculoskeletal, connective tissue and bone disorders	Arthralgia	Very rare
General disorders and administration site conditions	Fever, malaise, chill	Rare

During graft re-infection preventive therapy very rare cases of intolerance reactions may be linked to an interval increase between administrations.

Adverse reactions observed with other human immunoglobulin preparations: With human normal immunoglobulins adverse reactions such as chills, headache, dizziness, fever, vomiting, allergic reactions, nausea, arthralgia, low blood pressure and moderate low back pain may occur occasionally.

Rarely human normal immunoglobulins may cause a sudden fall in blood pressure and, in isolated cases, anaphylactic shock, even when the patient has shown no hypersensitivity to previous administration.

With human normal immunoglobulin, cases of reversible aseptic meningitis, reversible and rare cases of transient cutaneous reactions have been observed. Reversible haemolytic reactions have been observed in patients, especially those with blood groups A, B, and AB. Rarely, haemolytic anaemia/haemolysis, increase requiring transfusion may develop after high dose IVIg treatment.

Increase in serum creatinine level and/or acute renal failure have been observed.

Thromboembolic events have been reported in the elderly, in patients with signs of cerebral or cardiac ischemia, and in overweight and severely hypovolaemic patients.

Very rarely: Thromboembolic reactions such as myocardial infarction, stroke, pulmonary embolism, deep vein thromboses.

העלון לרופא המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס ע"י פניה לבעל הרישום, חברת קמהדע בע"מ (טל' 08-9406472).

להלן הקישור למאגר התרופות של משרד הבריאות:

<https://data.health.gov.il/drugs/index.html#/byDrug>

בברכה,
פנינה נודל,
רוקחת ממונה