KAMADA
High Quality Pharmaceuticals

דצמבר 2020

רופא/ה, רוקח/ת נכבד/ה,

חברת קמהדע מבקשת להודיע על עדכון עלון כמפורט להלן, עבור התכשירים:

Replenine-VF 500 ; Replenine-VF 1000

צורת מינון, צורת מתן: Powder for solution for injection, IV

מרכיבים פעילים בהתאם לרישיון:

Factor IX 50 IU/ml

Factor II 0.2 IU/ml

Factor X 1 IU/ml

המאושר להתוויה:

Treatment and prophylaxis of bleeding in patients with haemophilia B (congenital factor IX deficiency).

מהות השינוי: עדכון עלון לרופא. בהודעה זו מצוינים השינויים המהווים החמרה (הודגשו בצהוב). בעלון שינויים נוספים שאינם החמרה.

4.4 Special warnings and precautions for use

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Cardiovascular events

In patients with existing cardiovascular risk factors, substitution therapy with factor IX may increase the cardiovascular risk.

Catheter-related complications

If a central venous access device (CVAD) is required, risk of CVAD-related complications including local infections, bacteraemia and catheter site thrombosis should be considered.

Transmissible agents

…Appropriate vaccination (hepatitis A and B) should be considered for patients in regular/repeated receipt of human plasma-derived factor IX products.

4.8 Undesirable effects

Summary of the safety profile

Hypersensitivity or allergic reactions (which may include angioedema, burning and stinging at the infusion site, chills, flushing, generalised urticaria, headache, hives, hypotension, lethargy, nausea, restlessness, tachycardia, tightness of the chest, tingling, vomiting, wheezing) have been observed rarely. In some cases, these reactions have progressed to severe anaphylaxis (including shock), and they have occurred in close temporal association with development of factor IX inhibitors (see section 4.4). Nephrotic syndrome has been reported following attempted immune tolerance induction in haemophilia B patients with factor IX inhibitors and a history of allergic reaction.

Patients with haemophilia B may develop neutralising antibodies (inhibitors) to factor IX. If such inhibitors occur, the condition will manifest itself as an insufficient clinical response. In such cases, it is recommended that a specialised haemophilia centre be contacted.

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

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