אפריל 2020

רופא/ה, רוקח/ת נכבד/ה,

חברת קמהדע מבקשת להודיע על עידכון עלון כמפורט להלן, עבור התכשיר:

שם התכשיר:	**Haemoctin SDH 1000 IU** **המוקטין SDH 1000 יחב"ל**	**Haemoctin SDH 500 IU** **המוקטין SDH 500 יחב"ל**	**Haemoctin SDH 250 IU** **המוקטין SDH 250 יחב"ל**
מרכיבים פעילים:	Human plasma coagulation Factor VIII		
צורת מינון, צורת מתן: התויה ע"פ הרישיון:	Powder for Solution for Injection, IV Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency) In patient with acquired factor VIII deficiency. Haemoctin is not effective in controlling the bleeding of patients with Von Willebrand`s disease.		

מהות השינוי: עידכון עלון לרופא. הודעה זו כוללת החמרות (בצהוב). בעלון שינויים נוספים שאינם החמרה.

4.4 Special warnings and precautions for use

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Inhibitors

The formation of neutralising antibodies (inhibitors) to factor VIII is a known complication in the management of individuals with haemophilia A.

These inhibitors are usually IgG immunoglobulins directed against the factor VIII procoagulant activity, which are quantified in Bethesda Units (BU) per ml of plasma using the modified assay. The risk of developing inhibitors is correlated to the severity of the disease as well as the exposure to factor VIII, this risk being highest within the first 50 ~~20~~ exposure days but continues throughout life although the risk is uncommon.

~~Rarely, inhibitors may develop after the first 100 exposure days.~~

~~Cases of recurrent inhibitor (low titre) have been observed after switching from one factor VIII~~

~~product to another in previously treated patients with more than 100 exposure days who have a previous history of inhibitor development. Therefore, it is recommended to monitor all patients carefully for inhibitor occurrence following any product switch.~~

The clinical relevance of inhibitor development will depend on the titre of the inhibitor, with low titre posing less of a risk of insufficient clinical response than high titre inhibitors.

In general, all patients treated with coagulation factor VIII products should be carefully monitored for the development of inhibitors by appropriate clinical observations and laboratory tests. If the expected factor VIII activity plasma levels are not attained, or if bleeding is not controlled with an appropriate dose, testing for factor VIII inhibitor presence should be performed. In patients with high levels of inhibitor, factor VIII therapy may not be effective and other therapeutic options should be considered. Management of such patients should be directed by physicians with experience in the care of haemophilia and factor VIII inhibitors.

Paediatric population

The special warnings and precautions for use mentioned for the adults should also be considered for the paediatric population.

4.8 Undesirable effects

MedDRA Standard System Organ Class	**Adverse reactions**	**Frequency**
Blood and lymphatic system disorders	Factor VIII inhibition	uncommon (PTPs)* very common (PUPs)*
Immune system disorders	Anaphylactic shock, hypersensitivity	not known
Skin and subcutaneous tissue disorder	Erythema ~~Exanthema~~, pruritus,urticaria, ~~erythema~~	~~very rare~~ not known
~~Investigations~~	~~Anti factor VIII antibody positive~~	~~very rare~~

**Frequency is based on studies with all factor VIII products which included patients with severe haemophilia A. PTPs = previously-treated patients, PUPs = previously-untreated patients.*

Paediatric population

With exception of factor VIII inhibition, adverse reactions in children are expected to be the same as in adults (see table above).

5.1 Pharmacodynamic properties

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Of note, annualized bleeding rate (ABR) is not comparable between different factor concentrates and between different clinical studies.

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

בברכה,

צוות רישום קמהדע בע"מ

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