הודעה על החמרה (מידע בטיחות) בעלון לרופא (מעודכן 05.2013)

תאריך 5.4.17

שם תכשיר באנגלית ומספר הרישום

Haemoctin SDH 250 IU מספר רישום 121-05-30093

Haemoctin SDH 500 IU מספר רישום 121-06-30094

Haemoctin SDH 1000 IU מספר רישום 121-07-30095

שם בעל הרישום Kamada Ltd

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות

טקסט חדש	טקסט נוכחי	פרק בעלון
		Indication
		contraindications
Treatment should be ~~initiated~~ under the supervision of a physician experienced in the treatment of haemophilia. Previously untreated patients No data are available. Treatment monitoring During the course of treatment, appropriate determination of factor VIII levels is advised to guide the dose to be administered and the frequency of repeated infusions. Individual patients may vary in their response to factor VIII, demonstrating different half-lives and recoveries. Dose based on bodyweight may require adjustment in underweight or overweight patients. In the case of major surgical interventions in particular, precise monitoring of the substitution therapy by means of coagulation analysis (plasma factor VIII activity) is indispensable. When using an *in vitro* thromboplastin time (aPTT)-based one stage clotting assay for determining factor VIII activity in patients' blood samples, plasma factor VIII activity results can be significantly affected by both the type of aPTT reagent and the reference standard used in the assay. Also there can be significant discrepancies between assay results obtained by aPTT-based one stage clotting assay and the chromogenic assay according to Ph. Eur. This is of importance particularly when changing the laboratory and/or reagents used in the assay.	Treatment should be initiated under the supervision of a physician experienced in the treatment of haemophilia. During the course of treatment, appropriate determination of factor VIII levels is advised to guide the dose to be administered and the frequency of repeated infusions. In the case of major surgical interventions in particular, precise monitoring of the substitution therapy by means of coagulation analysis (plasma factor VIII activity) is indispensable. Individual patients may vary in their response to factor VIII, achieving different levels of *in vivo* recovery and demonstrating different half-lives.	Posology, dosage & administration

~~Patients should be monitored for the development of factor VIII inhibitors. If the expected factor VIII activity plasma levels are not attained, or if bleeding is not controlled with an appropriate dose, an assay should be performed to determine if a factor VIII inhibitor is present.~~ ~~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 only be directed by physicians with experience in the care of patients with haemophilia. See also 4.4.~~	Patients should be monitored for the development of factor VIII inhibitors. If the expected factor VIII activity plasma levels are not attained, or if bleeding is not controlled with an appropriate dose, an assay should be performed to determine if a factor VIII inhibitor is present. 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 only be directed by physicians with experience in the care of patients with haemophilia. See also 4.4.	
Previously untreated patients No data are available.		**CLINICAL PARTICULARS**
Inhibitors 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. Cardiovascular events In patients with existing cardiovascular risk factors, substitution therapy with factor VIII 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		**Special Warnings and Special Precautions for Use**
No interactions of human coagulation factor VIII products with other medicinal products ~~are known~~ have been reported.	No interactions of human coagulation factor VIII products with other medicinal products are known.	**Interaction with Other Medicaments and Other Forms of Interaction**
		Fertility, pregnancy and Lactation

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 ~~infrequently~~ rarely, and may in some cases progress to severe anaphylaxis (including shock). ~~On rare occasions, fever has been observed.~~	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 infrequently, and may in some cases progress to severe anaphylaxis (including shock). On rare occasions, fever has been observed.	**Adverse events**
~~From introduction in the market until January 2006 a total of about 500 000 standard dosages of Haemoctin® SDH 250, 500 and 1000 were applied. In total 12 cases of suspected development of inhibitors were received from clinical trials, spontaneous reporting and non interventional studies. This corresponds to a reporting frequency of 1 case on 40 864 applications.~~ ~~➢ 6 of these cases concern transient inhibitors.~~ ~~➢ In 9 cases the titres of inhibitors were below 10 BU and in 3 cases higher than 10 BU.~~ ~~➢ 5 cases concern inhibitor development in previously treated patients (PTPs), 3 cases concern inhibitor development in previously untreated patients (PUPs), 1 case concerned a minimally pretreated patient (16 ED) and in 3 cases exposure days were not reported.~~ ~~➢ 4 cases concern children under 6 years of age, in three of these cases~~ ~~➢ the inhibitors were transient.~~	From introduction in the market until January 2006 a total of about 500 000 standard dosages of Haemoctin® SDH 250, 500 and 1000 were applied. In total 12 cases of suspected development of inhibitors were received from clinical trials, spontaneous reporting and non interventional studies. This corresponds to a reporting frequency of 1 case on 40 864 applications. ➢ 6 of these cases concern transient inhibitors. ➢ In 9 cases the titres of inhibitors were below 10 BU and in 3 cases higher than 10 BU. ➢ 5 cases concern inhibitor development in previously treated patients (PTPs), 3 cases concern inhibitor development in previously untreated patients (PUPs), 1 case concerned a minimally pretreated patient (16 ED) and in 3 cases exposure days were not reported. ➢ 4 cases concern children under 6 years of age, in three of these cases ➢ the inhibitors were transient.	

MedDRA Standard System Organ Class	Adverse reactions	Frequency
~~Nervous system disorder~~	~~Haemorrhage brain~~	~~very rare~~
~~Blood and lymphatic system disorders~~	~~Anaemia~~	~~very rare~~
Skin and subcutaneous tissue disorder	Exanthema, urticaria, erythema	very rare
Investigations	Anti factor VIII antibody positive	very rare

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~~No cases of transmission of infective agents have been confirmed so far.~~	No cases of transmission of infective agents have been confirmed so far.	

~~In patients with high levels of inhibitor factor VIII therapy may not be effective, and other therapeutic options should be considered. Following such treatment options Haemoctin SDH has been shown to be effective in 11 patients with inhibitors undergoing immune tolerance therapy.~~ Data on successfully performed Immune Tolerance Induction (ITI) have been collected in patients with haemophilia A who have developed inhibitors to factor VIII.	In patients with high levels of inhibitor factor VIII therapy may not be effective, and other therapeutic options should be considered. Following such treatment options Haemoctin SDH has been shown to be effective in 11 patients with inhibitors undergoing immune tolerance therapy.	**Pharmacodynamic properties**
Incompatibilities In the absence of compatibility studies this medicinal product ~~Haemoctin® SDH 250, 500 or 1000~~ must not be mixed with other medicinal products. Only the provided infusion sets should be used because treatment failure can occur as a consequence of human coagulation factor VIII adsorption to the internal surfaces of some infusion equipment.	Haemoctin® SDH 250, 500 or 1000 must not be mixed with other medicinal products. Only the provided infusion sets should be used because treatment failure can occur as a consequence of human coagulation factor VIII adsorption to the internal surfaces of some infusion equipment.	**Pharmaceutical particulars**
~~**Instructions for use and handling, and disposal**~~ **Special precautions for disposal and other handling** Reconstituted medicinal product should be inspected visually for particulate matter and discoloration prior to administration. The solution should be clear or slightly opalescent. Do not use solutions that are cloudy or have deposits.	**Instructions for use and handling, and disposal** **…** Do not use solutions that are cloudy or contain visible particles.	