10/10/2020

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

הנדון: **FANHDI®25 IU/ML**
FANHDI® 50 IU/ML (FACTOR VIII)
FANHDI® 100 IU/ML 1000 IU/10 ML (FACTOR VIII)
FANHDI® 100 IU/ML, 1500 IU/15 ML (FACTOR VIII)
Powder and solvent for solution for injection.

חברת מדיצ'י מדיקל בע"מ מבקשת להודיע על עדכון העלון לרופא של התכשירים לעיל.

Therapeutic indications

Fanhdi® is indicated for the prevention and control of bleeding in patients with moderate or severe factor VIII deficiency due to classical hemophilia A.

Fanhdi® is not effective in controlling the bleeding of patients with von Willebrand's disease.

Qualitative and Quantitative Composition

Human coagulation factor VIII, Ph. Eur.

Fanhdi® is presented as a lyophilised powder for solution for injection containing nominally 250, 500, 1000 or 1500 IU human coagulation factor VIII per vial.

The product contains approximately 25, 50 or 100 IU/ml of human coagulation factor VIII when reconstituted with 10 ml of Water for Injections for the presentations of 250, 500 and 1000 IU. The presentation of 1500 IU is reconstituted with 15 ml of Water for Injections and contains approximately 100 IU/ml.

The factor VIII:C potency (IU) is determined using the European Pharmacopoeia chromogenic assay. The specific activity of Fanhdi® is at least 2.5 to 10 IU factor VIII:C/mg protein depending on its strength (250, 500, 1000 or 1500 IU).

For a full list of excipients, see section 6.1.

להלן עדכוני הבטיחות העיקריים: (מסומנים ברקע צהוב):

[...]

4.4 Special warnings and precautions for use

As with any intravenous protein product, allergic type hypersensitivity reactions are possible. The product contains traces of human proteins other than factor VIII. Patients should be informed of the early signs of hypersensitivity reactions including hives, generalised urticaria, tightness of the chest, wheezing, hypotension, and anaphylaxis. If these symptoms occur, they should be advised to discontinue use of the product immediately and contact their physician.

In case of shock, the current medical standards for shock-treatment should be observed.

Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens. The measures taken are

considered effective for enveloped viruses such as HIV, HBV and HCV. The measures taken may be of limited value against non-enveloped viruses such as HAV and parvovirus B19. Parvovirus B19 infection may be serious for pregnant women (foetal infection) and for individuals with immunodeficiency or increased erythropoiesis (e.g. haemolytic anaemia).

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 20 exposure days. 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 inhibitors which are transiently present or remain consistently 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.

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

It is strongly recommended that every time that Fanhdi® is administered to a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product.

Sodium content

The residual content of sodium in Fanhdi®, arising from the manufacturing process, does not exceed 23 mg per vial in the 250, 500 and 1000 IU presentations, and 34.5 mg per vial in the 1500 IU presentation. This is equivalent to 1.15% and 1.72% respectively of the recommended maximum daily intake of sodium for an adult. However, depending on the body weight of the patient and the posology, the patient may receive more than one vial.

[…]

העלון החדש מכיל עוד עדכונים. למידע נוסף יש לעיין בעלון החדש.

העלון העדכני נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:
https://data.health.gov.il/drugs/index.html#!/byDrug וניתן לקבלו מודפס על ידי פניה לחברת מדיצ'י מדיקל בע"מ, רח' המחשב 3 נתניה, בטלפון 09-7446170.

בברכה,

האלה ביאדסה - רוקחת ממונה