מאי 2020

רוקח/ת נכבד/ה
רופא/ה נכבד/ה,

הנדון: עדכון העלונים לרופא לתכשירים

Octanate 500 (138-11-31682)
Octanate 1000 (138-12-31683)
Powder and solvent for solution for injection

חומר פעיל: Active ingredient:

500 IU or 1000 IU Factor VIII per vial

להלן נוסח ההתוויה המאושר לתכשירים:

Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency).
This preparation does not contain von Willebrand factor in pharmacologically effective quantities and is therefore not indicated in von Willebrand's disease.

חברת דובר מיכשור רפואי ומדעי בע"מ מבקשת להודיע כי העלונים לרופא לתכשירי אוקטאנט עודכנו במאי 2020.

בהודעה זו מצוינים סעיפים בהם נעשו עדכונים המהווים החמרות - מודגש בצהוב. טקסט שנמחק מסומן בקו חוצה (~~טקסט~~), טקסט שהוסף מסומן בצבע (טקסט).
בעלונים קיימים עדכונים נוספים שאינם מהווים החמרות.

העלונים לרופא נשלחו למשרד-הבריאות לצורך פירסומם במאגר התרופות שבאתר משרד הבריאות וניתן לקבלם מודפסים על ידי פנייה לבעל הרישום: דובר מיכשור רפואי ומדעי בע"מ, רח' המעלות 11, הרצליה.

בברכה,
רבקה סלונים
רוקחת ממונה

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טל: 09-9514545 פקס: 09-9580151

העדכונים העיקריים בעלון לרופא:

2. Qualitative and Quantitative Composition

[…]
Produced from the plasma of human donors.
[…]

4.4 Special warnings and precautions for use

Traceability

In order to improve traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

[…]

Inhibitors

[…]

The risk of developing inhibitors is correlated to the severity of the disease as well as the exposure to ~~anti-haemophilic~~ factor VIII, this risk being highest within the first ~~20~~ 50 exposure days , but continues throughout life although the risk is uncommon.

~~Rarely, inhibitors may develop after the first 100 exposure days. Patients treated with human coagulation factor VIII should be carefully monitored for the development of inhibitory antibodies by appropriate clinical observations and laboratory test. See also 4.8. Undesirable effects~~

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.

Cardiovascular events

In patients with existing cardiovascular risk factors, substitution therapy with FVIII 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.

[…]

Paediatric population

The listed warnings and precautions apply to both adults and children.

4.8 Undesirable effects

הסעיף נערך מחדש. להלן ההחמרות:

MedDRA Standard System Organ Class	Adverse Reaction	Frequency
Blood and lymphatic system disorders	FVIII inhibition	Uncommon (PTPs)* Very common (PUPs)*

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

Paediatric population

Frequency, type and severity of adverse reactions in children are the same as in adults.

6.6 Special precautions for disposal and other handling

[…]

- Reconstituted medicinal product should be inspected visually for particulate matter and discoloration prior to administration.

[…]