MEDISON
Delivering Innovative Healthcare

פברואר 2021

הנדון: עדכון עלון לרופא עבור התכשיר
Defitelio®, concentrate for solution for infusion

רופא/ה, רוקח/ת נכבדים,
חברת מדיסון פארמה מבקשת ליידע על עדכון העלון לרופא לתכשיר *Defitelio®*

ההתוויה המאושרת:
Defitelio® is indicated for the treatment of severe hepatic veno-occlusive disease (VOD) also known as sinusoidal obstructive syndrome (SOS) in haematopoietic stem-cell transplantation (HSCT) therapy. It is indicated in adults and in adolescents, children and infants over 1 month of age.

העדכון מתייחס לכמות הסודיום שבתכשיר ועדכונים/תיקוני נוסח נוספים, בסעיף 4.8 ו- 5.1:

4. CLINICAL PARTICULARS
4.4 Special warnings and precautions for use
…
This medicinal product contains 20.4 mg sodium per vial, equivalent to 1.02% of the WHO recommended maximum daily intake of 2 g sodium for an adult.~~less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium-free".~~

4.8 Undesirable effects
Summary of the Safety Profile
The safety evaluation of defibrotide is based on the safety pooled data set, which included patients who received 25 mg/kg of defibrotide for the treatment of VOD, from 4 clinical studies: The Phase 3 pivotal treatment study (2005-01), the Treatment-IND study, the dose-finding study (99-118), and a controlled randomised prophylaxis study (2004-000592-33).
In the Phase 3 pivotal treatment study ~~(2005-01 Study)~~, the overall incidence of adverse events was similar in the defibrotide treatment group and in the control group (historical). The tabulated list of adverse reactions incorporates the ADRs observed in the safety pooled data set ~~study 2005-01~~ [ADR = any event reported as possibly related on at least two occasions] and TEAEs observed in the final completed Treatment-IND 2006-05 study [TEAE = any AE that started or worsened in severity after the first dose of defibrotide]. For adverse reactions reported ~~in both studies~~, the highest frequency was used in the table below. The safety data from the pivotal study are supported and confirmed with data from the completed Treatment-IND study.
…

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
…
Cardiac electrophysiology
Based on the results of the QTc study, conducted in healthy subjects at therapeutic and supra-therapeutic doses, it can be concluded that Defitelio® has no significant or clinically relevant QTc-prolonging potential at doses up to 2.4 times higher than therapeutically indicated. Defitelio® might be considered free of proarrhythmic toxicity related to QT changes.

העלון לרופא נמצא בקישור וכן נשלח לפרסום במאגר התרופות באתר משרד הבריאות וניתן לקבלו מודפס על ידי פניה לבעל הרישום.

בברכה,
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