ינואר 2022

רופא/ה, רוקח/ת נכבד/ה,

הנדון: **<u>עלוני התכשיר NovoEight 500 IU, 1000 IU & 2000 IU</u>**
<u>Powder and solvent for solution for injection</u>

חברת נובו נורדיסק בע"מ מבקשת ליידע על עדכון העלונים לרופא ולצרכן לתכשיר

<u>חומר פעיל:</u> turoctocog alfa
<u>ההתוויה הרשומה לתכשיר:</u>

Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency).
NovoEight can be used for all age groups.

בוצעו עדכונים לאורך העלון לרופא, בהודעה זו מצוינים העדכונים המהותיים בלבד.
טקסט עם <u>קו תחתי</u> מציין טקסט שהוסף לעלון ואילו טקסט עם ~~קו חוצה~~ מסמן טקסט שהורד מהעלון.

<u>עדכונים לעלון לרופא:</u>

4.2 Posology and method of administration

~~*Previously untreated patients*~~

~~The safety and efficacy of NovoEight in previously untreated patients have not yet been established. 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 injections. ~~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.~~ <u>demonstrating different half-lives and recoveries. Dose based on bodyweight may require adjustment in underweight or overweight patients.</u>

.
.
.

Prophylaxis

For long term prophylaxis against bleeding in patients with severe haemophilia A. The usual recommended doses are 20–40 IU of factor VIII per kg body weight every second day or 20–50 IU of factor VIII per kg body weight 3 times weekly. <u>In adults and adolesents (>12 years) with bleeding risk not greater than one episode a year or patients with low compliance to the higher frequency treatment, a less frequent regimen (40-60 IU/kg every third day or twice weekly) may be applicable.</u> In some cases, especially in younger patients, shorter dosage intervals or higher doses may be necessary.

4.8 Undesirable effects

changes in **Table 2 Frequency of adverse drug reactions in clinical trials** *and*

In clinical trials ~~studies~~ involving 63 previously treated paediatric patients between 0 and 12 years of age and 24 adolescents between 12 and 18 years of age with severe haemophilia A no difference in the safety profile of NovoEight was observed between paediatric patients and adults.

In the trial with previously untreated patients, between 0 and 6 years of age, a total of 46 adverse reactions were reported in 33 of 60 patients exposed to NovoEight. The most frequently reported adverse reaction was Factor VIII inhibition, see section 4.4. High risk genetic mutations were identified in 92.3% of the overall and 93.8% of the high titre confirmed inhibitors. No other factors were significantly associated with inhibitor development.

Changes throughout **5. PHARMACOLOGICAL PROPERTIES**

העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלם מודפסים על ידי פניה לבעל הרישום:
נובו נורדיסק בע"מ, רחוב עתיר ידע 1, כפר-סבא 4464301, ישראל
טלפון: 09-7630444, פקס: 09-7630456.

בברכה,

ויולט אנדריא
רוקחת ממונה
נובו נורדיסק בע"מ