02/2019

Vidaza Lyophilized Powder for Preparation for Injection

וידאזה אבקה מיובשת בהקפאה להכנת זריקות

רופא/ה, רוקח/ת נכבד/ה,

- העלון לרופא של המוצר עודכן בפברואר 2019
- בהודעה זו מצוינים השינויים המהותיים העיקריים. בעלון שינויים נוספים שאינם החמרה.
- טקסט שהתווסף מסומן בקו תחתי, טקסט שהוסר מסומן בקו חוצה

החומר הפעיל: Azacitidine 100 mg

להלן נוסח ההתוויה המאושר לתכשיר:

For the treatment of patients with the following FAB myelodysplastic syndromes subtypes: refractory anemia or refractory anemia with ringed sideroblasts (if accompanied by neutropenia or thrombocytopenia or requiring transfusions), refractory anaemia with excess blasts, refractory anaemia with excess blasts in transformation, and chronic myelomonocytic leukaema.

העדכון העיקרי בעלון לרופא נעשה בסעיף הבא:

3 DOSAGE AND ADMINISTRATION

~~2~~3.7 Instructions for Subcutaneous Administration

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Preparation for Immediate Subcutaneous Administration: ~~Doses greater than 4 mL should be divided equally into 2 syringes.~~ For doses requiring more than 1 vial, divide the dose equally between the syringes (e.g., dose 150 mg = 6 mL, 2 syringes with 3 mL in each syringe) and inject into two separate sites. Due to retention in the vial and needle, it may not be feasible to withdraw all of the suspension from the vial. The product may be held at room temperature for up to 1 hour, but must be administered within 1 hour after reconstitution.

Preparation for Delayed Subcutaneous Administration: The reconstituted product may be kept in the vial or drawn into a syringe. ~~Doses greater than 4 mL should be divided equally into 2 syringes. For instructions for storage of the reconstituted product please refer to section 14 - HOW SUPPLIED/STORAGE AND HANDLING: Storage. In case the product was refrigerated~~For doses requiring more than 1 vial, divide the dose equally between the syringes (e.g., dose 150 mg = 6 mL, 2 syringes with 3 mL in each syringe) and inject into two separate sites. Due to retention in the vial and needle, it may not be feasible to withdraw all of the suspension from the vial. The product must be refrigerated immediately. When VIDAZA is reconstituted using water for injection that has not been refrigerated, the reconstituted product may be held under refrigerated conditions (2ºC - 8ºC, 36ºF - 46ºF) for up to 8 hours. When VIDAZA is reconstituted using refrigerated (2ºC - 8ºC, 36ºF - 46ºF) water for injection, the reconstituted product may be stored under refrigerated conditions (2ºC - 8ºC, 36ºF - 46ºF) for up to 22 hours. After removal from refrigerated conditions, the suspension may be allowed to equilibrate to room temperature for up to 30 minutes prior to administration.

העלון לרופא נשלח למשרד-הבריאות לצורך העלאה למאגר התרופות שבאתר משרד-הבריאות וניתן לקבלו מודפס על ידי פנייה לבעל הרישום: ניאופרם בע"מ, רח' השילוח 6, ת.ד. 7063 פתח-תקווה, טל: 03-9373753.

בברכה,

עוז וולך
מנהל רגולציה ורוקח ממונה
ניאופרם בע"מ