01/2023

Vidaza וידאזה

רופא/ה, רוקח/ת נכבד/ה,
חברת ניאופרם בע"מ מבקשת להודיע על עדכון העלון לרופא של התכשיר שבנדון.
העלון עודכן בינואר 2023.

החומר הפעיל וכמותו: Azacitidine 100 mg

צורת מינון: Lyophilized Powder For Suspension For Sc Injection / Solution For Infusion

ההתוויה הרשומה לתכשיר בישראל:

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.

בהודעה זו מצוינים השינויים המהותיים בלבד.

מקראה לעדכונים המסומנים:

מידע שהוסר -מסומן בקו חוצה

תוספת – מסומנת בקו תחתון

תוספת החמרה - מסומנת בקו תחתון וכן במרקר צהוב

עדכונים מהותיים נערכו בסעיפים הבאים בעלון לרופא:

3. DOSAGE AND ADMINISTRATION

3.1 Important Administration Information

Do not substitute VIDAZA for oral azacitidine. The indications and dosing regimen for VIDAZA differ from that of oral azacitidine *[see Warnings and Precautions (5.1)]*

ניאופרם (ישראל) 1996 בע"מ בנין ניאופרם, רח' השילוח 6 ת.ד. 7063 פתח תקוה 4917001
Email: neopharm@neopharmisrael.com 03-9373716 :פקס 03-9373737 :טל www.neopharmgroup.com

3.9 Instructions for Intravenous Administration

Solution Stability:

VIDAZA reconstituted and diluted for intravenous administration may be stored at 25°C, but administration must be completed within 1 hour of reconstitution.

5. WARNINGS AND PRECAUTIONS

5.1 Risks of Substitution with Other Azacitidine Products

Due to substantial differences in the pharmacokinetic parameters *[see Clinical Pharmacology (12.3)]*, the recommended dose and schedule for VIDAZA are different from those of oral azacitidine products. Treatment of patients using VIDAZA at the recommended dosage of oral azacitidine may result in a fatal adverse reaction. Treatment of patients using oral azacitidine at the doses recommended for VIDAZA may not be effective.

Do not substitute VIDAZA for oral azacitidine *[see Dosage and Administration (~~2~~3.1)]*.

5.6 Embryo-Fetal ~~Risk~~ Toxicity

[…]

Advise pregnant women of the potential risk to a fetus. Advise females ~~with~~ of reproductive potential to ~~avoid pregnancy~~ use effective contraception during treatment with VIDAZA and for 6 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with VIDAZA and for 3 months after the last dose *~~[see Use in Specific Populations (7.3)]~~*. ~~Men should be advised to not father a child while receiving treatment with VIDAZA.~~ *[see Use in Specific Populations (7.1, 7.3)]*.

7. USE IN SPECIFIC POPULATIONS

7.2 Lactation

Risk Summary

There is no information regarding the presence of azacitidine in human milk, the effects of VIDAZA on the breastfed infant, or the effects of VIDAZA on milk production. Because many drugs are excreted in human milk and because of the potential for tumorigenicity shown for azacitidine in animal studies *[see Nonclinical Toxicology (11~~.1~~)]* and the potential for serious adverse reactions in nursing infants from VIDAZA, advise patients not to breastfeed during treatment with VIDAZA~~.~~ and for 1 week after the last dose.

7.3 Females and Males of Reproductive Potential

[…]

Contraception

Females

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to ~~avoid pregnancy~~use effective contraception during treatment with VIDAZA~~.~~ and for 6 months after the last dose.

Males

~~Males~~ Advise males with female ~~sexual~~ partners of reproductive potential ~~should not father a child and should~~ to use effective contraception during treatment with VIDAZA~~.~~ and for 3 months after the last dose.

קיימים עדכונים נוספים. למידע נוסף יש לעיין בעלון המעודכן לרופא.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום:
ניאופרם בע"מ, השילוח 6, ת.ד. 7063, פתח תקווה 4917001. טלפון: 03-9373737

בברכה,

אודיה צור

רוקחת ממונה
ניאופרם בע"מ