



אפריל 2023

רופא /ה, רוקח/ת נכבד/ה
חברת טבע מודיעה על העדכונים הבאים בעלון לצרכן (במתכונת עלון לרופא) של התכשיר

AZACITIDINE TEVA אזאציטידין טבע
LYOPHILIZED POWDER FOR SUSPENSION FOR SC INJECTION or
SOLUTION FOR IV INFUSION

Each vial contains: AZACITIDINE 100 MG

עדכונים בעלון לצרכן (במתכונת עלון לרופא)

התוויה כפי שאושרה בתעודת הרישום:

Azacitidine Teva is indicated for treatment of patients with the following French-American- British (FAB) myelodysplastic syndrome subtypes: refractory anemia (RA) or refractory anemia with ringed sideroblasts (if accompanied by neutropenia or thrombocytopenia or requiring transfusions), refractory anemia with excess blasts (RAEB), refractory anemia with excess blasts in transformation (RAEB-T), and chronic myelomonocytic leukemia (CMML).

ברצוננו להודיע שהעלון לרופא עודכן, בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות באדום):

3. DOSAGE AND ADMINISTRATION

3.1 Important Administration Information

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

[..]

3.9 Instructions for Intravenous Administration

Parenteral drug product should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. **Do not use the product if there is evidence of particulate matter or discoloration. Reconstitute the appropriate number of Azacitidine Teva vials to achieve the desired dose. Reconstitute each vial with 10 mL Sterile Water for Injection.** Vigorously shake or roll the vial until all solids are dissolved. The resulting solution will contain azacitidine 10 mg/mL. The solution should be clear.

[..]

טבע ישראל בע"מ.

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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)], the recommended dose and schedule for Azacitidine Teva are different from those of oral azacitidine products. Treatment of patients using Azacitidine Teva 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 Azacitidine Teva may not be effective.

Do not substitute Azacitidine Teva for oral azacitidine [see Dosage and Administration (3.1)].

[..]

5.6 Embryo-Fetal Toxicity

Based on the mechanism of action and findings in animals, Azacitidine can cause fetal harm when administered to a pregnant woman. Azacitidine administered to pregnant rats via a single intraperitoneal (IP) dose approximating 8% of the recommended human daily dose caused fetal death and anomalies.

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with Azacitidine and for 6 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with Azacitidine Teva and for 3 months after the last dose [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 Azacitidine on the breastfed infant, or the effects of Azacitidine 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)] and the potential for serious adverse reactions in nursing infants from Azacitidine, advise patients not to breastfeed during treatment with Azacitidine and for 1 week after the last dose.

7.3 Females and Males of Reproductive Potential

Based on its mechanism of action and findings in animals, Azacitidine can cause fetal harm when administered to a pregnant woman [see Use in Specific Populations (7.1)].

Pregnancy Testing

Verify the pregnancy status of females of reproductive potential prior to initiating Azacitidine.

Contraception

Females

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

Males

Advise males with female partners of reproductive potential to use effective contraception during treatment with Azacitidine and for 3 months after the last dose.

העלון לצרכן במתכונת עלון לרופא נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות
<https://israeldrugs.health.gov.il> וניתן לקבלו מודפס ע"י פניה לחברת טבע.