10/2021

רופא/ה, רוקח/ת נכבד/ה,

# איסטודקס - ISTODAX

**החומר הפעיל:** ROMIDEPSIN 10 MG/VIAL

**להלן נוסח ההתוויה המאושר לתכשיר:**

- Treatment of cutaneous T-cell lymphoma (CTCL) in patients who have received at least one prior systemic therapy.
- Treatment of peripheral T-cell lymphoma (PTCL) in patients who have received at least one prior therapy.

העלון לרופא במתכונת עלון לצרכן עודכן בספטמבר 2021.

בהודעה זו מצוינים השינויים המהווים החמרה. בעלונים שינויים נוספים שאינם החמרה.

טקסט שהתווסף מסומן בקו תחתי, טקסט שהוסר מסומן בקו חוצה.

**העדכונים העיקריים בעלון לרופא נעשו בסעיפים הבאים:**

## 5 WARNINGS AND PRECAUTIONS

### 5.5 Use in Pregnancy

~~There are no adequate and well-controlled studies of ISTODAX in pregnant women. However,~~ ~~based~~ Embryo-Fetal Toxicity

Based on its mechanism of action and findings from animal studies, ISTODAX can cause fetal harm when administered to a pregnant woman. In an animal reproductive study, romidepsin was embryocidal and caused adverse developmental outcomes at exposures below those in patients at the recommended dose of 14 mg/m$^2$. Advise females of reproductive potential to use effective contraception during treatment and for at least 1 month after the last dose. Advise males with female sexual partners of reproductive potential to use effective contraception during treatment and for at least 1 month after the last dose *[see Use in Specific Populations (8.1, 8.3) and Clinical Pharmacology (12.1)]*.

## 8 USE IN SPECIFIC POPULATIONS

### 8.1 Pregnancy

Risk Summary

…There are no available data on ISTODAX use in pregnant women to inform a drug associated risk of major birth defects and miscarriage. In an animal reproductive study, romidepsin was embryocidal and caused adverse developmental outcomes including embryo-fetal toxicity and malformations at exposures below those in patients at the recommended dose (see Data). Advise pregnant women of the potential risk to a fetus and to avoid becoming pregnant while receiving ISTODAX, and for at least 1 month after the last dose....

### 8.2 Lactation

Risk Summary

…advise lactating women not to breastfeed during treatment with ISTODAX and for at least 1 week after the last dose.

**8.3 Females and Males of Reproductive Potential**

ISTODAX can cause fetal harm when administered to a pregnant woman *[see Warnings and Precautions (5.5) and Use in Specific Populations (8.1)].*

**Pregnancy Testing**

Perform pregnancy testing in females of reproductive potential within 7 days prior to initiating therapy with ISTODAX.

**Contraception**

***Females***

Advise females of reproductive potential to use effective contraception during treatment with ISTODAX and for at least 1 month after the last dose. ISTODAX may reduce the effectiveness of estrogen-containing contraceptives. Therefore, alternative methods of non-estrogen containing contraception (e.g., condoms, intrauterine devices) should be used in patients receiving ISTODAX.

***Males***

Advise males with female partners of reproductive potential to use effective contraception and to avoid fathering a child during treatment with ISTODAX and for at least 1 month after the last dose.

Infertility

Based on findings in animals, romidepsin has the potential to affect male and female fertility *[see Nonclinical Toxicology (13.1)]*

*(….)*

**8.6 Hepatic Impairment**

… Monitor patients with hepatic impairment more frequently for toxicity, especially during the first cycle of therapy.

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**14. How Supplied**

ISTODAX is supplied as a kit including a sterile, lyophilized powder in a 10 mg single-dose vial containing 11 mg of romidepsin and 22 mg of the bulking agent, povidone, USP, and hydrochloric acid, NF, as pH adjuster….

העלון לרופא והעלון לצרכן נשלחו למשרד-הבריאות לצורך העלאתם למאגר התרופות שבאתר משרד-הבריאות וניתן לקבלם מודפסים על ידי פנייה לבעל הרישום: ניאופרם סיינטיפיק בע"מ, רח' השילוח 6, ת.ד. 7063 פתח-תקווה, טל: 03-9373753.

בברכה,

עוז וולך
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