ספטמבר 2026

Trodelvy® (sacituzumab govitecan 200 mg)
Powder for Concentrate for Solution for Infusion (170-64-37173-00)

צוות רפואי נכבד,

חברת גיליאד סיאנסז ישראל בע"מ, בשיתוף משרד הבריאות, מבקשת להביא לידיעתך את המידע שלהלן:

הנדון: עדכון עלון התכשיר Trodelvy® – המלצות מעודכנות למתן מניעה ראשונית באמצעות G-CSF בכל המטופלים הנמצאים בסיכון מוגבר לחום נויטרופני (Febrile Neutropenia)

סיכום

- Trodelvy עלול לגרום לנויטרופניה חמורה או מסכנת חיים, ונצפו זיהומים קטלניים משניים לנויטרופניה.
- העלון לרופא של Trodelvy עודכן כך שיכלול המלצה למתן טיפול מניעתי ראשוני באמצעות גורם מגרה יצירת מושבות גרנולוציטים (G-CSF) במטופלים הנמצאים בסיכון מוגבר לחום נויטרופני.

Summary

- Trodelvy can cause severe or life-threatening neutropenia and fatal infections secondary to neutropenia have been observed.
- An update has been made to the Prescriber Information (PI) of Trodelvy recommending primary prophylaxis with granulocyte colony stimulating factor (G-CSF) in patients at increased risk of febrile neutropenia.

Background

Therapeutic indications for Trodelvy:

- Trodelvy as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, including at least one of them for advanced disease.
- Trodelvy as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH−) breast cancer who have received endocrine-based therapy, and at least two additional systemic therapies in the advanced setting.

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You are reminded that Trodelvy can cause severe or life-threatening neutropenia. Fatal infections in the setting of neutropenia have been observed in clinical studies with Trodelvy, primarily in the first two cycles of treatment.

Neutropenia is listed with frequency very common (≥ 1/10) and febrile neutropenia is listed with frequency common (≥ 1/100 to < 1/10). Please see the PI for full details.

The PI of Trodelvy was recently updated, recommending primary prophylaxis with G-CSF in patients at increased risk of febrile neutropenia.

New evidence

In patients treated with Trodelvy, prophylaxis with G-CSF has been shown to reduce the risk of neutropenia and complications from neutropenia. In patients who received primary prophylaxis compared to those who did not, any Grade and Grade 3 and higher neutropenia was reduced by approximately half (31% vs 65% and 26% vs 50%, respectively). Primary prophylaxis with G-CSF should now be considered (PI Section 4.2 Posology and Method of Administration, Section 4.4 Special warnings and Precautions for Use, Section 4.8 Undesirable effects), starting in the first cycle of treatment with Trodelvy in patients at increased risk of febrile neutropenia.

Prescriber Action

- Primary prophylaxis with G-CSF should be considered starting with the first cycle of treatment in patients at increased risk of febrile neutropenia, for example older patients, patients with previous neutropenia, poor performance status, organ dysfunction, or multiple comorbidities.
- Consider treating neutropenia with G-CSF and consider prophylaxis in subsequent cycles as clinically indicated.
- Monitor absolute neutrophil count (ANC) during treatment. Trodelvy should not be administered if ANC is below 1500/mm^3 on Day 1 of any cycle or below 1000/mm^3 on Day 8 of any cycle. Withhold Trodelvy for neutropenic fever.
- Dose reductions for Trodelvy may be needed to manage neutropenia or febrile neutropenia.
- After the first instance, for subsequent Grade 3-4 febrile neutropenia events or subsequent prolonged Grade 3-4 neutropenia events, reduce one dose level with each recurrence or discontinue according to Table 1 (PI Section 4.2).

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Healthcare providers are advised to take this information into consideration when prescribing Trodelvy and discuss these risks with their patients and caregivers. Patients should be reminded that Trodelvy increases the risk of neutropenia and infections and to seek urgent medical attention at the first signs of fever or infection. This letter is not intended to be a complete description of the benefits and risks related to the use of Trodelvy. Please refer to the accompanying full PI for more information.

Call for reporting

Healthcare professionals should report any suspected adverse reactions associated with the use of Trodelvy to the Ministry of Health by clicking on the link "Report side effects due to medical treatment" that is located on the Ministry of Health homepage (www.health.gov.il) which redirects to the online form for reporting side effects, or by clicking on the link: https://sideeffects.health.gov.il

Additionally, adverse events can be reported to the Marketing Authorization Holder:

For reporting adverse events, please contact Gilead at the following email address: Safety_FC@gilead.com

For further information, please contact: medinfo.israel@gilead.com

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