יוני 2024

הנדון: JEMPERLI / ג'מפרלי

Dostarlimab 50mg/ml

Concentrate for solution for infusion

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

חברת גלקסוסמיתקליין ישראל בע"מ (GSK) מבקשת להודיע על עדכון העלון לצרכן ולרופא של התכשיר JEMPERLI / ג'מפרלי.

המרכיב הפעיל וחוזקו: Dostarlimab 50mg/ml

ההתוויה הרשומה לתכשיר בישראל:

JEMPERLI is indicated as monotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-containing regimen.

בהודעה זו מצויינים השינויים המהותיים שבוצעו לעלון .
מקרא לעדכונים המסומנים:

תוספת – כתב כחול , מחיקה-כתב אדום עם קו מחיקה

להלן העידכונים שנעשו בעלון לצרכן:

The following information is intended for healthcare professionals only:

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• For the 500 mg dose, withdraw 10 mL of JEMPERLI from a vial and transfer into an intravenous bag containing sodium chloride 9 mg/mL (0.9 %) solution for injection or glucose 50 mg/mL (5 %) solution for injection. The final concentration of the diluted solution should be between 2 mg/mL and 10 mg/mL. The total volume of the infusion solution must not exceed 250 mL. This may require withdrawing a volume of diluent from the IV bag prior to adding a volume of JEMPERLI into the IV bag.

- For example, if preparing a 500 mg dose in a 250 mL diluent IV bag, to achieve a 2 mg/mL concentration would require withdrawing 10 mL of diluent from the 250 mL IV bag. Then, 10 mL of JEMPERLI would be withdrawn from the vial and transferred into the IV bag.

• For the 1,000 mg dose, withdraw 10 mL of JEMPERLI from each of two vials (withdraw 20 mL total) and transfer into an intravenous bag containing sodium chloride 9 mg/mL (0.9 %) solution for injection or glucose 50 mg/mL (5 %) solution for injection. The final concentration of the diluted solution should be between ~~2~~ 4 mg/mL and 10 mg/mL. The total volume of the infusion solution must not exceed 250 mL. This may require withdrawing a volume of diluent from the IV bag prior to adding a volume of JEMPERLI into the IV bag.

- For example, if preparing a 1000 mg dose in a ~~500~~ 250 mL diluent IV bag, to achieve a ~~2~~ 4 mg/mL concentration would require withdrawing 20 mL of diluent from the ~~500~~ 250 mL IV bag. Then, 10 mL of JEMPERLI would be withdrawn from each of two vials, totaling 20 mL, and transferred into the the IV bag.

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להלן העידכונים שנעשו בעלון לרופא:

6.6 Special precautions for disposal and other handling

Preparation/dilution

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For the 500 mg dose, withdraw 10 mL of JEMPERLI from a vial and transfer into an intravenous bag containing sodium chloride 9 mg/mL (0.9 %) solution for injection, or glucose 50 mg/mL (5 %) solution for injection. The final concentration of the diluted solution should be between 2 mg/mL and 10 mg/mL. The total volume of the infusion solution must not exceed 250 mL. This may require withdrawing a volume of diluent from the intravenous bag prior to adding a volume of JEMPERLI into the IV bag.

-For example, if preparing a 500 mg dose in a 250 mL diluent intravenous bag, to achieve a 2 mg/mL concentration would require withdrawing 10 mL of diluent from the 250 mL intravenous bag. Then, 10 mL of JEMPERLI would be withdrawn from the vial and transferred into the intravenous bag.

For the 1000 mg dose, withdraw 10 mL of JEMPERLI from each of two vials (withdraw 20 mL total) and transfer into an intravenous bag containing sodium chloride 9 mg/mL (0.9 %) solution for injection, or glucose 50 mg/mL (5 %) solution for injection. The final concentration of the diluted solution should be between ~~2~~ 4 mg/mL and 10 mg/mL. The total volume of the infusion solution must not exceed 250 mL. This may require withdrawing a volume of diluent from the IV bag prior to adding a volume of JEMPERLI into the intravenous bag.

-For example, if preparing a 1000 mg dose in a ~~500~~ 250 mL diluent intravenous bag, to achieve a ~~2~~ 4 mg/mL concentration would require withdrawing 20 mL of diluent from the ~~500~~ 250 mL intravenous bag. Then, 10 mL of JEMPERLI would be withdrawn from each of two vials, totaling 20 mL, and transferred into the intravenous bag.

קיימים עדכונים נוספים. למידע נוסף יש לעיין בעלון לצרכן ולרופא המעודכנים.
העלונים לצרכן ולרופא מצורפים להודעה זו.
העלונים לצרכן ולרופא נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות:
https://www.old.health.gov.il/units/pharmacy/trufot/index.asp?safa=h וניתן לקבלם מודפסים על-ידי פניה לחברת גלקסוסמיתקליין
רח' בזל 25 פתח תקוה בטלפון: 03-9297100.
בברכה,

ליליאנה בלטר
רוקחת ממונה