דצמבר 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 לרופא של התכשיר JEMPERLI / ג'מפרלי.

המרכיב הפעיל וחוזקו: Dostarlimab 50mg/ml

ההתוויה הרשומה לתכשיר בישראל:

JEMPERLI is indicated in combination with carboplatin and paclitaxel for the treatment of adult patients with mismatch repair deficient (dMMR)/ microsatellite instability-high (MSI-H) primary advanced or recurrent endometrial cancer (EC) and who are candidates for systemic therapy.

JEMPERLI is indicated as monotherapy for the treatment of adult patients with dMMR/MSI-H recurrent or advanced EC that has progressed on or following prior treatment with a platinum-containing regimen.

מקרא לעדכונים המסומנים:

מידע שהוסר – מסומן בקו אדום חוצה ~~XXX~~

תוספת – כתב **כחול**

להלן העידכונים שנעשו בעלון לרופא:

4.2 Posology and method of administration

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Table 3. Recommended dose modifications for JEMPERLI		
Immune-related adverse reactions	**Severity grade[a]**	**Dose modification**
Colitis	2 ~~to~~ or 3	Withhold dose. Restart dosing when toxicity resolves to grade 0 or 1.
	4	Permanently discontinue.
Hepatitis	Grade 2 with AST[b] or ALT[c] > 3 and up to 5 × ULN[d] or total bilirubin > 1.5 and up to 3 × ULN	Withhold dose. Restart dosing when toxicity resolves to grade 0 ~~to~~or 1.
	Grade ≥ 3 with AST or ALT > 5 × ULN or total bilirubin > 3 × ULN	Permanently discontinue (see exception below)[e].
Type 1 diabetes mellitus (T1DM)	3 ~~to~~or 4 (hyperglycaemia)	Withhold dose. Restart dosing in appropriately managed, clinically and metabolically stable patients.

Table 3. Recommended dose modifications for JEMPERLI		
Immune-related adverse reactions	**Severity grade[a]**	**Dose modification**
Hypophysitis or adrenal insufficiency	2 ~~to~~, 3 or 4	Withhold dose. Restart dosing when toxicity resolves to grade 0 ~~to~~or 1. Permanently discontinue for recurrence or worsening while on adequate hormonal therapy.
Hypothyroidism or hyperthyroidism	3 ~~to~~or 4	Withhold dose. Restart dosing when toxicity resolves to grade 0 ~~to~~or 1.
Pneumonitis	2	Withhold dose. Restart dosing when toxicity resolves to grade 0~~-~~ or 1. If grade 2 recurs, permanently discontinue.
	3 ~~to~~or 4	Permanently discontinue.
Nephritis	2	Withhold dose. Restart dosing when toxicity resolves to grade 0~~-~~ or 1.
	3 ~~to~~or 4	Permanently discontinue.
~~Immune-mediated rash~~ Exfoliative dermatologic conditions (e.g. SJS, TEN, DRESS)	~~3~~ Suspected	Withhold dose~~.~~ for any grade. Restart dosing if not confirmed and when toxicity resolves to grade 0~~-~~ or 1.
	Confirmed~~4~~	Permanently discontinue.
Myocarditis	2, 3 or 4	Permanently discontinue.
Severe neurological toxicities (myasthenic syndrome/myasthenia gravis, Guillain-Barré syndrome, encephalitis, transverse myelitis)	2, 3 or 4	Permanently discontinue.
Other immune-related adverse reactions (including but not limited to myositis, ~~myocarditis, encephalitis, demyelinating neuropathy including Guillain-Barré syndrome~~, sarcoidosis, autoimmune haemolytic anaemia, pancreatitis, iridocyclitis, uveitis, diabetic ketoacidosis, arthralgia, solid organ transplant rejection, graft-versus-host disease)	3	Withhold dose. Restart dosing when toxicity resolves to grade 0~~-~~ or 1.
	4	Permanently discontinue.
Recurrence of immune-related adverse reactions after resolution to ≤ grade 1 (except for pneumonitis, see above)	3 ~~to~~or 4	Permanently discontinue.
Other adverse reactions	**Severity grade[a]**	**Dose modification**

Table 3. Recommended dose modifications for JEMPERLI		
Immune-related adverse reactions	**Severity grade[a]**	**Dose modification**
Infusion-related reactions	2	Withhold dose. If resolved within 1 hour of stopping, may be restarted at 50 % of the original infusion rate, or restart when symptoms resolve with pre-medication. If grade 2 recurs with adequate premedication, permanently discontinue.
	3 ~~to~~or 4	Permanently discontinue.

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למידע נוסף יש לעיין בעלון לרופא המעודכן.

העלון לרופא מצורף להודעה זו.

העלון לרופא נשלח 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