

אוגוסט 2025

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,**הריני להודיעכם כי העלון של התכשיר עודכן:****LIBTAYO****ליבטאיו**

Concentrate for solution for infusion

מרכיב פעיל : Cemiplimab

התוויות מאושרות:**Cutaneous Squamous Cell Carcinoma**

LIBTAYO as monotherapy is indicated for the treatment of adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation.

Basal Cell Carcinoma

LIBTAYO as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic basal cell carcinoma (laBCC or mBCC) who have progressed on or are intolerant to a hedgehog pathway inhibitor (HPI).

Non-Small Cell Lung Cancer

LIBTAYO as a single agent is indicated for the first-line treatment of adult patients with NSCLC whose tumors have high PD-L1 expression [Tumor Proportion Score (TPS) \geq 50%] as determined by an approved test, with no EGFR, ALK or ROS1 aberrations, and is:

- locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or
- metastatic.

LIBTAYO in combination with platinum-based chemotherapy is indicated for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) expressing PD-L1 (in \geq 1% of tumour cells), with no EGFR, ALK or ROS1 aberrations and is:

- locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or
- metastatic.

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להלן העדכונים בעלון לרופא המהווים החמרות (בכחול) :

4.2 Posology and method of administration

Table 1: Recommended treatment modifications			
Adverse reaction ^a	Severity ^b	Dose modification	Additional intervention
Immune-mediated adverse reactions			
[...]			
Other immune-mediated adverse reactions (including but not limited to paraneoplastic encephalomyelitis, meningitis, myositis, solid organ transplant rejection, graft-vs-host disease, GuillainBarre syndrome, central nervous system inflammation, chronic inflammatory demyelinating polyradiculoneuropathy, encephalitis, myasthenia gravis, neuropathy peripheral, myocarditis, pericarditis, immune thrombocytopenic purpura, vasculitis, arthralgia, arthritis, muscular weakness, myalgia, polymyalgia rheumatica, Sjogren's syndrome, keratitis, stomatitis, thyroiditis <u>and haemophagocytic lymphohistiocytosis</u>)	Grade 3 clinical signs or symptoms of an immune-related adverse reaction not described above	Withhold LIBTAYO	Initiate symptomatic management
		Resume LIBTAYO if other immune-mediated adverse reaction improves and remains at Grade 0 to 1 after corticosteroid taper to ≤10 mg/day prednisone or equivalent	
	<ul style="list-style-type: none"> - Grade 4 adverse reaction (excluding endocrinopathies) - <u>Confirmed haemophagocytic lymphohistiocytosis</u> - Recurrent severe Grade 3 immune-mediated adverse reaction - Persistent Grade 2 or 3 immune-mediated adverse reactions lasting 12 weeks or longer (excluding endocrinopathies) - Inability to reduce corticosteroid dose to 10 mg or less of prednisone or equivalent per day within 12 weeks 	Permanently discontinue	Initial dose of 1 to 2 mg/kg/day prednisone or equivalent followed by a taper

העלון לרופא נמצא בקישור וכן הועבר לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום.

בברכה,
מדיסון פארמה בע"מ