

אפריל 2022

רופא/ה נכבד/ה

רוקח/ת נכבד/ה שלום רב,

פרסום עדכון בעלון התכשיר :

Imfinzi 120 mg 159-97-35280-00

Imfinzi 500 mg 159-98-35281-00

חברת אסטרזהניקה ישראל מבקשת להודיע על עדכון עלון בהתאם להוראות משרד הבריאות בתאריך **אפריל 2022**.

Durvalumab 120 mg, 500mg

הרכב:

התוויה:

Urothelial Carcinoma -IMFINZI is indicated for the treatment of patients with PD-L1 high (Tumor cell \geq 25% or IC \geq 25%) locally advanced or metastatic urothelial carcinoma who:

- have disease progression during or following platinum-containing chemotherapy.
- have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum containing chemotherapy.

Non-Small Cell Lung Cancer -IMFINZI is indicated for the treatment of patients with unresectable Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

Small Cell Lung Cancer -IMFINZI, in combination with etoposide and either carboplatin or cisplatin, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

העדכון העיקרי בעלון לרופא הוא:

1. DOSAGE AND ADMINISTRATION

Table 1. Recommended Dosages of IMFINZI

Indication	Recommended IMFINZI dosage	Duration of Therapy
Urothelial Carcinoma	Patients with a body weight of 30 kg and more:	Until disease progression or unacceptable toxicity

	<p>10 mg/kg every 2 weeks or 1500 mg every 4 weeks</p> <p>Patients with a body weight of less than 30 kg: 10 mg/kg every 2 weeks</p>	
<p>Unresectable stage III NSCLC</p>	<p>Patients with a body weight of 30 kg and more: 10 mg/kg every 2 weeks Or 1500 mg every 4 weeks</p> <p>Patients with a body weight of less than 30 kg: 10 mg/kg every 2 weeks or 20 mg/kg every 4 weeks</p>	<p>Until disease progression, unacceptable toxicity, or a maximum of 12 months</p>
<p>ES-SCLC</p>	<p>Patients with a body weight of 30 kg and more: 1500 mg¹ in combination with chemotherapy¹ every 3 weeks (21 days) for 4 cycles, followed by 1500 mg every 4 weeks as a single agent</p> <p>Patients with a body weight of less than 30 kg: 20 mg/kg in combination with chemotherapy every 3 weeks (21 days) for 4 cycles, followed by 20 mg/kg every 4 weeks as a single agent</p>	<p>Until disease progression or unacceptable toxicity</p>

¹ ~~Patients with a body weight of 30 kg or less must receive weight-~~

~~based dosing, equivalent to IMFINZI 20 mg/kg in combination with chemotherapy every 3 weeks (21 days) for 4 cycles, followed by 20 mg/kg every 4 weeks as a single agent until weight increases to greater than 30 kg.~~

¹ Administer IMFINZI prior to chemotherapy on the same day. When IMFINZI is administered in combination with chemotherapy, refer to the Prescribing Information for etoposide and carboplatin or cisplatin for dosing information.

העלונים מפורסמים במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על ידי פניה לבעל הרישום.
הוספת טקסט מהותי מסומנת בצבע. מחיקת טקסט מסומנת בקו חוצה.

בכבוד רב,

שרית רוזן
רוקחת ממונה
אסטרזהניקה (ישראל) בע"מ

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