

פרסום עדכון בעלוני התכשיר : Lynparza 100mg, 150mg

חברת אסטרזניקה ישראל מתכבדת להודיעך על אישור שתי התוויות חדשות עבור
: Lynparza (Olaparib)

First-line Maintenance Treatment of Advanced Ovarian Cancer in Combination with Bevacizumab

Lynparza is indicated in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either:

- a deleterious or suspected deleterious BRCA mutation, and/or
- genomic instability

BRCA1/2 or ATM- Gene-mutated Metastatic Castration-Resistant Prostate Cancer

Lynparza is indicated for the treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA1/2 or ATM- mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone.

הרכב:

Olaparib 100mg
Olaparib 150mg

התוויות מאושרות:

Ovarian cancer

Lynparza is indicated as monotherapy for the:

- maintenance treatment of adult patients with advanced (FIGO stages III and IV) BRCA1/2- mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.
- Maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete response or partial response) to platinum-based chemotherapy.

Germline BRCA-mutated HER2-negative Metastatic Breast Cancer

Lynparza is indicated in patients with deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)- positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy.

First-Line Maintenance Treatment of Germline BRCA-mutated Metastatic Pancreatic Adenocarcinoma

Lynparza is indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen.

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BRCA1/2 or ATM- Gene-mutated Metastatic Castration-Resistant Prostate Cancer

Lynparza is indicated for the treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA1/2 or ATM- mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone.

מעבר למידע הנוגע להתוויות החדשות שנסופו לעלונים, חלו גם העדכונים הבאים:

העדכונים המהותיים בעלון לרופא הם:

4.8 Undesirable effects

MedDRA System Organ Class	Adverse reactions	
	Frequency of All CTCAE grades	Frequency of CTCAE grade 3 and above
Blood and lymphatic system disorders	Very common Anaemia ^a Neutropenia ^a , Thrombocytopenia ^a , Leukopenia ^a Common Lymphopenia ^a	Very common Anaemia ^a Common Neutropenia ^a , Thrombocytopenia ^a , Leukopenia ^a Uncommon Lymphopenia ^a
Immune system disorders	Common Rash ^a Uncommon Hypersensitivity ^a , Dermatitis ^a , Angioedema*	-
Metabolism and nutrition disorders	Very common Decreased appetite	Uncommon Decreased appetite
Nervous system disorders	Very common Dizziness, Headache, Dysgeusia	Uncommon Dizziness, Headache
Respiratory, thoracic and mediastinal disorders	Very common Cough ^a , Dyspnoea ^a	Common Dyspnoea ^a Uncommon Cough ^a
Gastrointestinal disorders	Very common Vomiting, Diarrhoea, Nausea, Dyspepsia, Upper abdominal pain Common Stomatitis ^a	Common Vomiting, Diarrhoea, Nausea Uncommon Stomatitis ^a , Upper abdominal pain
Skin and subcutaneous tissue disorders	Rare Erythema nodosum	-
General disorders and administration site conditions	Very common Fatigue (including asthenia)	Common Fatigue (including asthenia)

MedDRA System Organ Class	Adverse reactions	
	Frequency of All CTCAE grades	Frequency of CTCAE grade 3 and above
Investigations	Common blood creatinine increased Uncommon Mean cell volume increased	Uncommon blood creatinine increased

העדכונים המהותיים בעלון לצרכן הם:

4. תופעות לוואי

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תופעות לוואי שכיחות מאוד (משפיעות על יותר מ- 1 מתוך 10 מטופלים):

- תחושת קוצר נשימה, תחושת עייפות מאוד גדולה, חיורון או דופק מהיר - אלו יכולים להיות תסמינים של ספירת דם נמוכה (אנמיה).

תופעות לוואי שאינן שכיחות (משפיעות על עד 1 מתוך 100 מטופלים):

- תגובות אלרגיות (לדוגמה: **נפיחות של הפנים, השפתיים, הלשון או הגרון, חרלת, קשיי נשימה או בליעה, סחרחורת העלולים להוות סימנים ותסמינים של תגובת רגישות יתר**).
- **תופעות לוואי נדירות (משפיעות על עד 1 מתוך 1000 מטופלים)**
- **דלקת ברקמת השומן מתחת לעור, אשר גורמת לכאב.**

מקרא לעדכונים המסומנים

הוספת טקסט מהותי מסומנת בצבע צהוב. מחיקת טקסט מסומנת בקו חוצה

העלונים מפורסמים במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על ידי פניה לבעל הרישום.

בכבוד רב,

שרית רוזן

רוקחת ממונה

אסטרזהניקה (ישראל) בע"מ

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