Answers That Matter.

אוגוסט 2021

רופא/ה נכבד/ה
רוקח/ת נכבד/ה

חברת אלי לילי מבקשת להודיעכם על עדכון עלון לרופא של התכשירים Verzenio 50 mg, 100 mg 150 mg, 200 mg.
שינויים המהווים החמרה מסומנים בצהוב.
העלון לרופא המעודכן מפורסם במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס על ידי פנייה לבעל הרישום :
אלי לילי ישראל בע"מ, השיזף 4, רעננה , טל': 09-9606234

בברכה,
רונן שוורץ
רוקח ממונה

Verzenio Film-Coated tablets
ורזניו טבליות מצופות
Verzenio 50 mg, (Abemaciclib 50 mg) film-coated tablets for oral use.
Verzenio 100 mg, (Abemaciclib 100 mg) film-coated tablets for oral use.
Verzenio 150 mg, (Abemaciclib 150 mg) film-coated tablets for oral use.
Verzenio 200 mg, ((Abemaciclib 200 mg) film-coated tablets for oral use.

התוויה המאושרת לתכשיר:

VERZENIO™ (abemaciclib) is indicated:

- in combination with a non-steroidal aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.
- in combination with fulvestrant for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy.
- as monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy in the metastatic setting and prior chemotherapy in the metastatic setting including taxane in adjuvant or metastatic setting.

Verzenio should not be used in women after prior treatment with cyclin-dependent kinases 4 and 6 (CDK4 and CDK6) inhibitor.

להלן העדכונים העיקריים בעלון לרופא:

3. DOSAGE AND ADMINISTRATION

3.2 Dose Modification

Table 5: VERZENIO Dose Modification and Management for ~~Other Toxicities~~[a] Interstitial Lung Disease/Pneumonitis

CTCAE Grade	VERZENIO Dose Modifications
Grade 1 or 2	No dose modification is required.
Persistent or recurrent Grade 2 toxicity that does not resolve with maximal supportive measures within 7 days to baseline or Grade 1	Suspend dose until toxicity resolves to baseline or ≤Grade 1. Resume at *next lower dose*.
Grade 3 or 4	~~Suspend dose until toxicity resolves to baseline or ≤Grade 1.~~ ~~Resume at *next lower dose*~~. Discontinue VERZENIO.

Eli Lilly Israel LTD. 4 HaSheizaf St.
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Tel: 972-9-9606234, Fax: 972-9-9576001

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Table 6: VERZENIO Dose Modification and Management for Other Toxicities[a]

CTCAE Grade	VERZENIO Dose Modifications
Grade 1 or 2	No dose modification is required.
Persistent or recurrent Grade 2 toxicity that does not resolve with maximal supportive measures within 7 days to baseline or Grade 1	Suspend dose until toxicity resolves to baseline or ≤Grade 1. Resume at *next lower dose*.
Grade 3 or 4	Suspend dose until toxicity resolves to baseline or ≤Grade 1. Resume at *next lower dose*.

[a] Excluding diarrhea, hematologic toxicity, ~~and~~ hepatotoxicity and ILD/pneumonitis.

6 WARNINGS AND PRECAUTIONS

6.3 Interstitial Lung Disease (ILD)/Pneumonitis

[….]

Dose interruption or dose reduction is recommended for patients who develop persistent or recurrent Grade 2 ILD/pneumonitis. Permanently discontinue VERZENIO in all patients with Grade 3 or 4 ILD or pneumonitis [see Dosage and Administration (3.2)].

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