פייזר פרמצבטיקה ישראל בע"מ
רח' שנקר 9, הרצליה פיתוח, ישראל 4672509
טל: 972-9-9700500 פקס: 972-9-9700501

אוגוסט 2026

רופא/ה, רוקח/ת נכבד/ה,
ברצוננו להודיעך על עדכון בעלון לרופא של תכשירי **טלזנה 0.1 מ"ג, טלזנה 0.25 מ"ג וטלזנה 1 מ"ג**. הודעתנו כוללת עדכון המידע עבור מטופלים עם Hepatic Impairment.

<u>המרכיב הפעיל:</u>
Talazoparib (as tosylate) 0.1 mg; talazoparib (as tosylate) 0.25 mg; talazoparib (as tosylate) 1 mg

<u>צורת מינון:</u>

Hard capsules

<u>התוויות מאושרות:</u>

<u>Talzenna 0.1 mg:</u>

HRR Gene-mutated Metastatic Castration-Resistant Prostate Cancer (mCRPC)

TALZENNA is indicated in combination with enzalutamide for the treatment of adult patients with homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC).

<u>Talzenna 0.25 mg:</u>

***BRCA*-mutated (g*BRCA*m) HER2-negative Locally Advanced or Metastatic Breast Cancer**

TALZENNA is indicated for the treatment of adult patients with deleterious or suspected deleterious germline breast cancer susceptibility gene (*BRCA*) mutated (g*BRCA*m) human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer.

HRR Gene-mutated Metastatic Castration-Resistant Prostate Cancer (mCRPC)

TALZENNA is indicated in combination with enzalutamide for the treatment of adult patients with homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC).

<u>Talzenna 1 mg:</u>

***BRCA*-mutated (g*BRCA*m) HER2-negative Locally Advanced or Metastatic Breast Cancer**

TALZENNA is indicated for the treatment of adult patients with deleterious or suspected deleterious germline breast cancer susceptibility gene (*BRCA*) mutated (g*BRCA*m) human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer.

<u>להלן העדכונים העיקריים בעלון לרופא:</u>

8 USE IN SPECIFIC POPULATIONS

8.6 Hepatic Impairment

<u>No dose adjustment is required for patients with mild hepatic impairment (total bilirubin ≤ 1 × upper limit of normal [ULN] and aspartate aminotransferase (AST) > ULN, or total bilirubin > 1.0 to</u>

1.5 × ULN and any AST), moderate hepatic impairment (total bilirubin > 1.5 to 3.0 × ULN and any AST), or severe hepatic impairment (total bilirubin > 3.0 × ULN and any AST) (see section 12.3). Talzenna in combination with enzalutamide is not recommended for use in patients with severe hepatic impairment (Child-Pugh classification C), as pharmacokinetics and safety have not been established in these patients (see section 12.3).
~~TALZENNA has not been studied in patients with moderate hepatic impairment (total bilirubin >1.5 to 3.0 × upper limit of normal [ULN] and any aspartate aminotransferase [AST]) or severe hepatic impairment (total bilirubin >3.0 × ULN and any AST). No dose adjustment is required for patients with mild hepatic impairment (total bilirubin ≤1 × ULN and AST > ULN, or total bilirubin >1.0 to 1.5 × ULN and any AST) *[see Clinical Pharmacology (12.3)]*.~~

12 CLINICAL PHARMACOLOGY

12.3 Pharmacokinetics

Patients with Hepatic Impairment
Talazoparib monotherapy
Based on a population PK analysis that included 490 patients who received talazoparib 1 mg daily as monotherapy, where 118 patients had mild hepatic impairment (total bilirubin ≤ 1.0 × ULN and AST > ULN, or total bilirubin > 1.0 to 1.5 × ULN and any AST), mild hepatic impairment had no effect on the PK of talazoparib. The PK of talazoparib in patients with normal hepatic function, mild hepatic impairment, moderate hepatic impairment (total bilirubin > 1.5 to 3.0 × ULN and any AST) or severe hepatic impairment (total bilirubin > 3.0 × ULN and any AST) was studied in a PK study. Population PK analysis using data from this PK study indicated that mild, moderate or severe hepatic impairment had no significant impact on the PK of talazoparib (see section 8.6).

Talazoparib co-administered with enzalutamide
The PK of talazoparib in combination with enzalutamide has not been studied in patients with hepatic impairment (see section 8.6).
~~Mild hepatic impairment (total bilirubin ≤1.0 × ULN and AST > ULN, or total bilirubin >1.0 to 1.5 × ULN and any AST) had no effect on the PK of talazoparib. The PK of talazoparib have not been studied in patients with moderate (total bilirubin >1.5 to 3.0 × ULN and any AST) or severe hepatic impairment (total bilirubin >3.0 × ULN and any AST).~~

השינויים מסומנים בקו תחתון עבור תוספת מידע ובקו חוצה עבור השמטת מידע. למידע מלא יש לעיין בעלון.

העלונים המעודכנים מפורסמים במאגר התרופות שבאתר משרד הבריאות: מאגר התרופות.

לחילופין, לקבלת עלון מלא מודפס ניתן לפנות לחברת פייזר פרמצבטיקה ישראל בע"מ, שנקר 9, ת.ד. 12133 הרצליה פיתוח, 4672509.

בברכה,
מרגריטה אוליבסון פולישצ'וק
רוקחת ממונה