ינואר 2025

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

חברת אלי לילי ישראל בע"מ מבקשת להודיעכם כי העלון לרופא של התכשיר Retevmo עודכן.

בהודעה זו נכללים השינויים המהותיים בלבד. שינויים המהווים החמרה מסומנים בצהוב, מידע שהתווסף מסומן בכחול ומידע שהוסר מסומן באדום. ישנם עדכונים נוספים.

העלון המעודכן לרופא מפורסם במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס על ידי פנייה לבעל הרישום:

אלי לילי ישראל בע"מ, רח' השיזף 4, רעננה , טל': 09-9606234

בברכה,

יצחק תירוש
רוקח ממונה

Retevmo 40 mg **רטבמו 40 מ"ג**

Retevmo 80 mg **רטבמו 80 מ"ג**

צורת מינון: Capsules

החומר הפעיל: Selpercatinib 40 and 80 mg

התוויה המאושרת לתכשיר:

Metastatic *RET* Fusion-Positive Non-Small Cell Lung Cancer
RETEVMO is indicated for the treatment of adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC).

***RET*-Mutant Medullary Thyroid Cancer**
RETEVMO is indicated for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy.

***RET* Fusion-Positive Thyroid Cancer**
RETEVMO is indicated for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic *RET* fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).

Other *RET* Fusion-Positive Solid Tumors
RETEVMO as monotherapy is indicated for the treatment of adults with advanced *RET* fusion-positive solid tumors, when treatment options not targeting *RET* provide limited clinical benefit, or have been exhausted.

העדכונים העיקריים בעלון לרופא הינם:

7 DRUG INTERACTIONS
7.2 Effects of RETEVMO on Other Drugs

Certain P-gp and BCRP Substrates

RETEVMO is a P-gp and BCRP inhibitor. Concomitant use of RETEVMO with P-gp or BCRP substrates increases their plasma concentrations *[see Clinical Pharmacology (12.3)]*, which may increase the risk of adverse reactions related to these substrates. Avoid coadministration of RETEVMO with P-gp or BCRP substrates where minimal concentration changes may lead to increased adverse reactions. If coadministration cannot be avoided, follow recommendations for P-gp and BCRP substrates provided in their approved product labeling.

Eli Lilly Israel Ltd. 4 HaSheizaf St.
P.O.Box 4246 Ra'anana 4366411
Tel: 09-9606234

אלי לילי ישראל בע"מ, רח' השיזף 4
ת.ד. 4246 רעננה 4366411
טלפון: 09-9606234

8.4 Pediatric Use

The safety and effectiveness of RETEVMO have been established in pediatric patients ~~aged~~ 12 years of age and older for the treatment of:

- advanced or metastatic medullary thyroid cancer (MTC) with a *RET* mutation who require systemic therapy
- advanced or metastatic thyroid cancer ~~*RET* fusion-positive thyroid cancer~~ with a *RET* gene fusion who require systemic therapy and are radioactive iodine-refractory (if radioactive iodine is appropriate)
- locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options.

Use of RETEVMO for these indications is supported by evidence from adequate and well-controlled studies in ~~adults~~ adult and pediatric patients with additional pharmacokinetic and safety data in pediatric patients ~~aged~~ 12 years of age and older *[see Adverse Reactions (6.1), Clinical Pharmacology (12.3), Clinical Studies (14.2, 14.3~~)~~, 14.4)].* The predicted exposures of selpercatinib in pediatric patients at the recommended dosages were within the range of values predicted in patients ≥ 12 years and ≥ 50 kg in body weight receiving the approved recommended dosage of 160 mg twice daily [see Clinical Pharmacology (12.3)].