J-C Health Care Ltd.

Johnson&Johnson

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ספטמבר 2026

רופא/ה נכבד/ה
רוקח/ת נכבד/ה
הנדון: רייברבנט 50 מ"ג/מ"ל תוך ורידי | Rybrevant 50 mg/ml IV

בעל הרישום .J-C Health Care Ltd מבקש להודיעכם על שינוי שם התכשיר ועדכון משטר המינון.

העלון לרופא של התכשיר שבנדון עודכן בספטמבר 2026 .

פרטי העדכון העיקריים מופיעים בהמשך (קו תחתי משמעו תוספת טקסט, טקסט שנמחק מסומן ~~בקו חוצה~~).

ההתוויות המאושרות בישראל:

First-Line Treatment of NSCLC with *EGFR* Exon 19 Deletions or Exon 21 L858R Substitution Mutations
RYBREVANT in combination with lazertinib, is indicated for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, as detected by an approved test. *[see Dosage and Administration (5.2)]*.

Previously Treated NSCLC with *EGFR* Exon 20 Insertion Mutations
RYBREVANT is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutation, as detected by an approved test *[see Dosage and Administration (5.2)]*, whose disease has progressed on or after platinum-based chemotherapy.

First line treatment of NSCLC with EGFR Exon 20 Insertion Mutations
RYBREVANT is indicated in combination with carboplatin and pemetrexed for the first-line treatment of adultpatients with locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer (NSCLC) with activating epidermal-growth factor receptor (EGFR) Exon 20 insertion mutations.

Previously Treated NSCLC with *EGFR* Exon 19 Deletions or Exon 21 L858R Substitution Mutations
RYBREVANT is indicated in combination with carboplatin and pemetrexed for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal-growth factor receptor (EGFR) Exon 19 deletions or Exon 21 L858R substitution mutations, whose disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor (TKI).

מרכיב פעיל: Amivantamab

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:
https://israeldrugs.health.gov.il/#!/byDrug.

כמו כן, מצורף לפרסום זה וניתן לקבל העתק מודפס שלו באמצעות פנייה לבעל הרישום: ג'יי.סי הלת'קר בע"מ , קיבוץ שפיים, 6099000, טל': 09-9591111.

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מומלץ לקרוא בעיון את כל תוכן העלונים ולעדכן את המטופלים במידע הרלוונטי להם.

<u>העדכונים העיקריים בעלון:</u>

1 NAME OF THE MEDICINAL PRODUCT

RYBREVANT
50 mg/mL <u>I.V</u> ~~concentrate for solution for infusion~~.

5 DOSAGE AND ADMINISTRATION
[…]
5.2 Patient Selection

Select patients for treatment with RYBREVANT based on the presence of a mutation as detected by an approved test.

Table 1: Patient Selection

Indication	Treatment Regimen	Source for Testing
First-Line Treatment of NSCLC with EGFR Exon 19 Deletions or Exon 21 L858R Substitution Mutations *[see Indications and Usage (1.1)]*	RYBREVANT in combination with lazertinib	• <u>Before initiation of Rybrevant therapy, EGFR mutation status in tumor tissue or plasma specimens must be established using a validated test method. If no mutation is detected in a plasma specimen, tumor tissue should be tested if available in sufficient amount and quality due to the potential for false negative results using a plasma-test.</u> • ~~Tumor or plasma specimens.~~ • Testing may be performed at any time from initial diagnosis. • Testing does not need to be repeated once EGFR mutation status has been established.
First-Line Treatment of NSCLC with EGFR Exon 20 Insertion Mutations *[see Indications and Usage (4.2)]*	RYBREVANT in combination with carboplatin and pemetrexed	
Previously Treated NSCLC with EGFR Exon 20 Insertion Mutations *[see Indications and Usage (4.3)]*	RYBREVANT as a single agent	