

LUMAKRAS® is the only once-daily, oral KRAS G12C therapy with an FDA-confirmed starting dose of 960 mg^{1,2}

ONCE-DAILY ORAL

LUMAKRAS®

(sotorasib) tablets
320 mg | 240 mg | 120 mg

Reduce patient pill burden with the 240 mg tablet vs 120 mg tablet for managing dose modifications¹

- Treat until disease progression or unacceptable toxicity¹
- Patients should take the daily dose at the same time each day, with or without food¹



240 mg tablet (yellow)^{1,3}

LUMAKRAS® tablets are comparable in size to a dime. Tablet as seen may not reflect actual size, scale to dime is accurate³

Other tablet options:

- 320 mg tablet (beige)^{1,3}
- 120 mg tablet (yellow)^{1,3}

In the CodeBreakK 100 registrational trial (N=204)

- 5% of patients experienced a **dose reduction** due to an adverse reaction¹
- 34% of patients experienced a **dosage interruption** due to an adverse reaction¹

Recommended dose reductions for adverse reactions¹

- If adverse reactions occur, a maximum of 2 dose reductions are permitted

Starting dose options¹



4 × 240 mg tablets once daily¹

- OR 3x 320 mg tablets once daily
OR 8x 120 mg tablets once daily

Dose reductions for adverse reactions¹

First Dose Reduction¹
(480 mg)

- OR 2X 240 mg tablets once daily
4X 120 mg tablets once daily

Second Dose Reduction¹
(240 mg)

- OR 1X 240 mg tablets once daily
2X 120 mg tablets once daily

Dose modifications for adverse reactions¹

Hepatotoxicity

AST or ALT > 3 × and up to 5 × ULN (or > 3 × and up to 5 × baseline if baseline abnormal) with symptoms
OR
AST or ALT > 5 × ULN (or > 5 × baseline if baseline abnormal)

- Withhold LUMAKRAS® until recovery to ≤ 3 × ULN or to ≤ 3 × baseline if baseline abnormal
- Resume LUMAKRAS® at the next lower dose level

AST or ALT > 3 × ULN with total bilirubin > 2 × ULN

- Permanently discontinue LUMAKRAS® if no alternative cause is identified
- If alternative cause is identified, do not resume LUMAKRAS® until AST/ALT/bilirubin return to baseline

ILD/pneumonitis

Any grade suspected

- Withhold LUMAKRAS® and permanently discontinue if confirmed

Nausea or vomiting

Despite appropriate supportive care

Grade 3-4

- Withhold LUMAKRAS® until recovered to ≤ Grade 1 or baseline. After recovery, resume LUMAKRAS® at the next lower dose level

Diarrhea

Despite appropriate supportive care

Grade 3-4

Other adverse reactions

Grade 3-4

- LUMAKRAS® should be discontinued if patients are unable to tolerate the minimum dose of 240 mg once daily¹
- No clinically meaningful differences in the pharmacokinetics of LUMAKRAS® were observed based on age, sex, race, body weight, line of therapy, ECOG PS, mild and moderate renal impairment, or mild hepatic impairment¹
- No dosage modification is recommended in patients with mild-to-moderate hepatic impairment (Child-Pugh A or B)¹
 - The effect of severe hepatic impairment (Child-Pugh C) on the safety of LUMAKRAS® is unknown. Monitor for LUMAKRAS® adverse reactions in patients with hepatic impairment more frequently since these patients may be at increased risk for adverse reactions, including hepatotoxicity¹
- No dose adjustment is required on the basis of age¹

INDICATION

LUMAKRAS® is indicated for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy.

This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Please see Important Safety Information for LUMAKRAS® on next page.

ALT, alanine transaminase; AST, aspartate transaminase; ECOG PS, Eastern Cooperative Oncology Group performance status; ILD, interstitial lung disease; KRAS, Kirsten rat sarcoma viral oncogene homolog; ULN, upper limit of normal.

Administration to patients who have difficulty swallowing solids¹



- Disperse tablets in 120 mL (4 ounces) of non-carbonated, room-temperature water without crushing. No other liquids should be used. Stir or swirl the cup for approximately 3 minutes until tablets are dispersed into small pieces (the tablets will not completely dissolve) and drink immediately or within 2 hours. The appearance of the mixture may range from pale yellow to bright yellow. Swallow the dispersed tablet. Do not chew pieces of the tablet. Rinse the container with an additional 120 mL (4 ounces) of water and drink. If the mixture is not consumed immediately, stir the mixture again to ensure that tablets are dispersed

IMPORTANT SAFETY INFORMATION

Hepatotoxicity

- LUMAKRAS[®] can cause hepatotoxicity and increased ALT or AST which may lead to drug-induced liver injury and hepatitis.
- In the pooled safety population of NSCLC patients who received single agent LUMAKRAS[®] 960 mg hepatotoxicity occurred in 27% of patients, of which 16% were Grade \geq 3. Among patients with hepatotoxicity who required dosage modifications, 64% required treatment with corticosteroids.
- In this pooled safety population of NSCLC patients who received single agent LUMAKRAS[®] 960 mg, 17% of patients who received LUMAKRAS[®] had increased alanine aminotransferase (ALT)/increased aspartate aminotransferase (AST); of which 9% were Grade \geq 3. The median time to first onset of increased ALT/AST was 6.3 weeks (range: 0.4 to 42). Increased ALT/AST leading to dose interruption or reduction occurred in 9% of patients treated with LUMAKRAS[®]. LUMAKRAS[®] was permanently discontinued due to increased ALT/AST in 2.7% of patients. Drug-induced liver injury occurred in 1.6% (all grades) including 1.3% (Grade \geq 3).
- In this pooled safety population of NSCLC patients who received single agent LUMAKRAS[®] 960 mg, a total of 40% patients with recent (\leq 3 months) immunotherapy prior to starting LUMAKRAS[®] had an event of hepatotoxicity. An event of hepatotoxicity was observed in 18% of patients who started LUMAKRAS[®] more than 3 months after last dose of immunotherapy and in 17% of those who never received immunotherapy. Regardless of time from prior immunotherapy, 94% of hepatotoxicity events improved or resolved with dosage modification of LUMAKRAS[®], with or without corticosteroid treatment.
- Monitor liver function tests (ALT, AST, alkaline phosphatase and total bilirubin) prior to the start of LUMAKRAS[®], every 3 weeks for the first 3 months of treatment, then once a month or as clinically indicated, with more frequent testing in patients who develop transaminase and/or bilirubin elevations. Withhold, reduce the dose or permanently discontinue LUMAKRAS[®] based on severity of the adverse reaction. Consider administering systemic corticosteroids for the management of hepatotoxicity.

Interstitial Lung Disease (ILD)/Pneumonitis

- LUMAKRAS[®] can cause ILD/pneumonitis that can be fatal.
- In the pooled safety population of NSCLC patients who received single agent LUMAKRAS[®] 960 mg ILD/pneumonitis occurred in 2.2% of patients, of which 1.1% were Grade \geq 3, and 1 case was fatal. The median time to first onset for ILD/pneumonitis was 8.6 weeks (range: 2.1 to 36.7 weeks). LUMAKRAS[®] was permanently discontinued due to ILD/pneumonitis in 1.3% of LUMAKRAS[®]-treated patients. Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis (e.g., dyspnea, cough, fever). Immediately withhold LUMAKRAS[®] in patients with suspected ILD/pneumonitis and permanently discontinue LUMAKRAS[®] if no other potential causes of ILD/pneumonitis are identified.

Most Common Adverse Reactions

- The most common adverse reactions \geq 20% were diarrhea, musculoskeletal pain, nausea, fatigue, hepatotoxicity, and cough.

Drug Interactions

- Advise patients to inform their healthcare provider of all concomitant medications, including prescription medicines, over-the-counter drugs, vitamins, dietary and herbal products.
- Inform patients to avoid proton pump inhibitors and H₂ receptor antagonists while taking LUMAKRAS[®].
- If coadministration with an acid-reducing agent cannot be avoided, inform patients to take LUMAKRAS[®] 4 hours before or 10 hours after a locally acting antacid.

Please see full [Prescribing Information for LUMAKRAS[®]](#).

References: 1. LUMAKRAS[®] (sotorasib) prescribing information, Amgen. 2. Hochmair MJ, et al. *Eur J Cancer*. 2024;208:114204. 3. Data on file, Amgen [Sotorasib Tablet Size].

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