LUMAKRAS® is the only once-daily, oral *KRAS* G12C therapy and has an FDA-confirmed starting dose of 960 mg orally[1,2]

- Treat until disease progression or unacceptable toxicity[1]
- **Patients should take the daily dose of LUMAKRAS® at the same time each day, with or without food[1]**

×4

240 mg yellow tablets once daily[1]

LUMAKRAS® tablets are comparable in size to a dime.[1,3]

LUMAKRAS® (sotorasib) 240 mg tablets

Dose modifications

5% of patients experienced a dose reduction due to an adverse reaction in CodeBreaK 100 (N=204)[1]

- 34% of patients experienced a dosage interruption due to an adverse reaction

Confirmed starting dose (960 mg)

4 × 240 mg tablets once daily

First dose reduction (480 mg)

2 × 240 mg tablets once daily

Second dose reduction (240 mg)

1 × 240 mg tablets once daily

If ARs occur, a maximum of two dose reductions is permitted[1]

Dose modifications for adverse reactions[1]

Hepatotoxicity		ILD/pneumonitis	Nausea or vomiting	Diarrhea	Other adverse reactions
			Despite supportive care	Despite supportive care	Despite supportive care
AST or ALT > 3 x and up to 5 x baseline if baseline abnormal with symptoms **or** AST or ALT > 5 x ULN (or > 5 x baseline if baseline abnormal)	AST or ALT > 3 x ULN with total bilirubin > 2 x ULN	Any grade suspected	Grades 3–4	Grades 3–4	Grades 3–4
◦ Withhold LUMAKRAS® until recovered to ≤ 3 x ULN or to ≤ 3 x baseline if baseline is abnormal ◦ Resume LUMAKRAS® at the next lower dose level	◦ 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	◦ Withhold LUMAKRAS® and permanently discontinue if confirmed	◦ Withhold LUMAKRAS® until recovered to ≤ Grade 1 or baseline. After recovery, resume LUMAKRAS® at the next lower dose level		

- LUMAKRAS® should be discontinued if patients are unable to tolerate the minimum dose of 240 mg once daily[1]
- 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 (eGFR ≥ 30 mL/min/1.73 m^2), or mild hepatic impairment (AST or ALT < 2.5 x ULN or total bilirubin < 1.5 x ULN)[1]
- No dose adjustment 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 adverse reactions with LUMAKRAS® in patients with hepatic impairment more frequently since these patients may be at increased risk for adverse reactions, including hepatotoxicity[1]
- No dose adjustment is required on the basis of age[1]

ALT, alanine transaminase; AR, adverse reaction; AST, aspartate transaminase; ECOG PS, Eastern Cooperative Oncology Group performance status; eGFR, estimated glomerular filtration rate; ILD, interstitial lung disease; *KRAS*, Kirsten rat sarcoma viral oncogene homolog; ULN, upper limit of normal.

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 back side.

Administration to patients who have difficulty swallowing solids[1]

- 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 ≥ 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 ≥ 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 ≥ 3).
- In this pooled safety population of NSCLC patients who received single agent LUMAKRAS® 960 mg, a total of 40% patients with recent (≤ 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 ≥ 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 ≥ 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 H_2 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 accompanying 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]; 2023.

Visit LumakrasHCP.com to learn more

AMGEN

LUMAKRAS® (sotorasib) 240 mg tablets