LUMAKRAS® (sotorasib) product fact sheet

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).

Description

240 mg tablets; yellow, oval-shaped, immediate release, film-coated, debossed with **"AMG"** on one side and **"240"** on the opposite side

How supplied

NDC	Strength	Quantity
55513-512-60	**240 mg**	**1 bottle of 120 tablets** with child-resistant closure

Storage and handling

Store at 20°C to 25°C (68°F to 77°F). Excursions permitted from 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]

Supplied and marketed by

Amgen USA Inc.
LUMAKRAS.com

Product returns

For information and instructions regarding product returns, please contact your wholesaler or Amgen Trade Operations at 1-800-28-AMGEN (1-800-282-6436). Credit for returns is subject to Amgen's current Product Return Policy.

Product information

Medical Information: 1-800-77-AMGEN (1-800-772-6436)

For questions on coverage or co-pay assistance:
Amgen SupportPlus: (866) 264-2778 or AmgenSupportPlus.com/hcp

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.

Please see page 3 for LUMAKRAS® full Important Safety Information.
Please see LUMAKRAS® full Prescribing Information.

LUMAKRAS®
(sotorasib) 240 mg tablets

AMGEN® Support+

We're right here, right when you need us

Personalized support that you and your patients can count on across Amgen therapies.

HCP Support Center

Our Amgen® SupportPlus Representatives can assist with issues around patient coverage, prior authorizations, co-pay programs, and more.

Field Reimbursement Specialist

A Field Reimbursement Specialist can provide live or virtual coverage and access resources to support your patients.

Financial Support

We know every patient has unique needs. And we're here to provide financial support information and resources, regardless of their current financial situation or type of insurance they have.

Call Amgen SupportPlus at (866) 264-2778, Monday-Friday, 9:00 am - 8:00 pm ET or visit **AmgenSupportPlus.com**.

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- 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 LUMAKRAS® full Prescribing Information.

Reference: LUMAKRAS (sotorasib) prescribing information, Amgen.

For more information, visit LUMAKRASHCP.com

AMGEN

Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799
www.amgen.com

LUMAKRAS®
(sotorasib) 240 mg tablets

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