

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



120 mg tablets: yellow, oblong-shaped, immediate release, film-coated, debossed with "AMG" on one side and "120" on the opposite side¹



320 mg tablets: beige, oval-shaped, immediate release, film-coated, debossed with "AMG" on one side and "320" on the opposite side¹

Product information

NDC	Strength	Quantity
55513-488-24	120 mg	1 bottle of 240 tablets with child-resistant closure ¹
55513-504-50	320 mg	1 bottle of 90 tablets with child-resistant closure ¹

Storage requirements

- 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]¹

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](https://www.amgen.com/supportplus)

IMPORTANT SAFETY INFORMATION

Hepatotoxicity

- LUMAKRAS can cause hepatotoxicity, which may lead to drug-induced liver injury and hepatitis.
- Among 357 patients who received LUMAKRAS in CodeBreak 100, hepatotoxicity occurred in 1.7% (all grades) and 1.4% (grade 3). A total of 18% of patients who received LUMAKRAS had increased alanine aminotransferase (ALT)/increased aspartate aminotransferase (AST); 6% were grade 3 and 0.6% were grade 4. In addition to dose interruption or reduction, 5% of patients received corticosteroids for the treatment of hepatotoxicity.
- Monitor liver function tests (ALT, AST, 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, dose reduce, or permanently discontinue LUMAKRAS based on severity of adverse reaction.

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

LUMAKRAS®
(sotorasib) 120 mg tablets
320 mg tablets

Support programs

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.



Amgen® Access Specialists

An Amgen Access 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](https://www.amgen.com/supportplus).

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Interstitial Lung Disease (ILD)/Pneumonitis

- LUMAKRAS can cause ILD/pneumonitis that can be fatal. Among 357 patients who received LUMAKRAS in CodeBreak 100 ILD/pneumonitis occurred in 0.8% of patients, all cases were grade 3 or 4 at onset, and 1 case was fatal. LUMAKRAS was discontinued due to ILD/pneumonitis in 0.6% of patients.
- Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis (eg, 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.

Reference: 1. LUMAKRAS (sotorasib) prescribing information, Amgen.

Please see LUMAKRAS full **Prescribing Information**.

For more information, visit [LUMAKRASHCP.com](https://www.lumakrashcp.com)

AMGEN[®]

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www.amgen.com

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320 mg tablets

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