ALUNBRIG®

BRIGATINIB

180mg | 90mg | 30mg

TABLETS

ACCESS GUIDE

INDICATIONS AND USAGE

ALUNBRIG is a kinase inhibitor indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.

Please see Important Safety Information on pages 4 to 5 and accompanying full Prescribing Information.

Please see **page 3** for information about Takeda Oncology Here2Assist™.

DISTRIBUTION DETAILS FOR ALUNBRIG

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Product details

Product name	Distributed and marketed by
ALUNBRIG tablets, for oral use	Takeda Pharmaceuticals America, Inc.
Storage and handling	**Recommended dosing**
Store at controlled room temperature 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) (see USP)	90 mg orally once daily for the first 7 days; then increase the dose to 180 mg orally once daily

How supplied

Strength	Count
180 mg	○ Bottle of 30 tablets NDC 63020-180-30
90 mg	○ Bottle of 30 tablets NDC 63020-090-30
30 mg	○ Bottle of 30 tablets NDC 63020-113-30
Initiation pack: 90 mg and 180 mg Contains the first-month supply of the recommended dosing regimen to assist patients starting on ALUNBRIG	○ One carton containing 1 bottle of 90 mg tablets (7 count)* and 1 bottle of 180 mg tablets (23 count)* NDC 63020-198-30
ALUNBRIG tablets are supplied in high-density, polyethylene bottles with screw-top closures	

Ordering

For accounts not using a Medically Integrated Pharmacy (MIP), ALUNBRIG can be ordered from the following specialty pharmacies:

Specialty Pharmacies†

- **Biologics**
  1-800-850-4306
  biologics.mckesson.com
- **Onco360 Specialty Pharmacy**
  1-877-662-6633
  onco360.com

Accounts dispensing through an MIP may purchase ALUNBRIG through the following distribution partners:

Distribution Partners for Qualified Entities‡

- **ASD Healthcare**
  1-800-746-6273
  asdhealthcare.com
- **Cardinal Health**
  1-877-453-3972
  cardinalhealth.com
- **McKesson Specialty Care**
  1-800-482-6700
  mckesson.com
- **McKesson Plasma and Biologics**
  1-877-625-2566
  mckesson.com
- **Oncology Supply**
  1-800-633-7555
  oncologysupply.com

NDC, National Drug Code; USP, United States Pharmacopeia.

*180 mg bottle of 23 tablets (NDC 63020-180-23) and 90 mg bottle of 7 tablets (NDC 63020-090-07) are available as part of the Initiation Pack, but aren't available for individual sale.

†ALUNBRIG must be filled through one of these in-network specialty pharmacies. Sending an ALUNBRIG prescription to a pharmacy that is either not your institution's medically integrated pharmacy or outside of the limited distribution network may result in delay or nonfulfillment of the prescription.

‡Qualified entities for direct purchase include hospitals, physician practices, and institutions that have been licensed by a state agency to dispense pharmaceutical products to appropriate patients. Direct purchase is not available to specialty pharmacy providers or retail pharmacies who are not themselves part of a qualified entity. Eligible government entities include the Department of Defense, Department of Veterans Affairs, and 340B covered entities.

Takeda Oncology Here2Assist®

We're here to help your patients with their coverage, financial, and educational resource needs

Committed to supporting your patients

Takeda Oncology Here2Assist® is a comprehensive support program committed to helping your patients navigate coverage requirements, identify available financial assistance, and connect with helpful resources throughout their Takeda Oncology treatment.

- Works with your patients' insurance company to help get your patient started on their medication
- Identifies available financial assistance that may be right for your patients
- Identifies specialty pharmacies to help fill and ship your patients' prescriptions appropriately
- Conducts regular follow-up calls to patients

Visit us at https://www.here2assist.com/hcp to learn more

Daryl
Takeda Oncology Here2Assist® patient

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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Interstitial Lung Disease (ILD)/Pneumonitis

Severe, life-threatening, and fatal pulmonary adverse reactions consistent with interstitial lung disease (ILD)/pneumonitis have occurred with ALUNBRIG. In ALTA 1L, ILD/pneumonitis occurred in 5.1% of patients receiving ALUNBRIG. ILD/pneumonitis occurred within 8 days of initiation of ALUNBRIG in 2.9% of patients, with Grade 3 to 4 reactions occurring in 2.2% of patients. In the ALTA study, at the approved dose (90→180 mg), ILD/pneumonitis occurred in 9.1% of patients. Monitor for new or worsening respiratory symptoms (dyspnea, cough, etc.), particularly during the first week of initiating ALUNBRIG. Withhold ALUNBRIG in any patient with new or worsening respiratory symptoms, and promptly evaluate for ILD/pneumonitis or other causes of respiratory symptoms (e.g., pulmonary embolism, tumor progression, and infectious pneumonia). For Grade 1 or 2 ILD/pneumonitis, either dose reduce or permanently discontinue ALUNBRIG. Permanently discontinue ALUNBRIG for Grade 3 or 4 ILD/pneumonitis or recurrence of Grade 1 or 2 ILD/pneumonitis.

Hypertension

In ALTA 1L, hypertension was reported in 32% of patients receiving ALUNBRIG; 13% of patients experienced Grade 3 hypertension. Control blood pressure prior to treatment with ALUNBRIG. Monitor blood pressure and withhold ALUNBRIG for Grade 3 hypertension despite optimal antihypertensive therapy. Consider permanent discontinuation of treatment with ALUNBRIG for Grade 4 hypertension or recurrence of Grade 3 hypertension. Use caution when administering ALUNBRIG in combination with antihypertensive agents that cause bradycardia.

Bradycardia

In ALTA 1L, heart rates less than 50 beats per minute (bpm) occurred in 8.1% of patients receiving ALUNBRIG; one patient (0.7 %) experienced Grade 3 bradycardia. Monitor heart rate and blood pressure during treatment with ALUNBRIG. For symptomatic bradycardia, withhold ALUNBRIG and review concomitant medications for those known to cause bradycardia; dose reduce concomitant medication or ALUNBRIG as appropriate. Discontinue ALUNBRIG for life-threatening bradycardia if no contributing concomitant medication is identified.

Visual Disturbance

In ALTA 1L, Grade 1 or 2 adverse reactions leading to visual disturbance, including blurred vision, photophobia, photopsia, and reduced visual acuity, were reported in 7.4% of patients receiving ALUNBRIG. In the ALTA study, at the approved dose (90→180 mg), Grade 3 macular edema and cataract occurred in one patient each. Advise patients to report any visual symptoms. Withhold ALUNBRIG and obtain an ophthalmologic evaluation in patients with new or worsening visual symptoms of Grade 2 or greater severity; upon recovery, dose reduce as appropriate. Permanently discontinue treatment with ALUNBRIG for Grade 4 visual disturbances.

Creatine Phosphokinase (CPK) Elevation

In ALTA 1L, creatine phosphokinase (CPK) elevation occurred in 81% of patients who received ALUNBRIG. The incidence of Grade 3 or 4 CPK elevation was 24%. Dose reduction for CPK elevation occurred in 15% of patients. Advise patients to report any unexplained muscle pain, tenderness, or weakness. Monitor CPK levels during ALUNBRIG treatment. Withhold ALUNBRIG for Grade 3 or 4 CPK elevation with Grade 2 or higher muscle pain or weakness. Upon resolution or recovery to Grade 1 CPK elevation or baseline, resume ALUNBRIG at the same dose or at a reduced dose.

Pancreatic Enzyme Elevation

In ALTA 1L, amylase elevation occurred in 52% of patients and Grade 3 or 4 amylase elevation occurred in 6.8% of patients who received ALUNBRIG. Lipase elevations occurred in 59% of patients and Grade 3 or 4 lipase elevation occurred in 17% of patients. Monitor lipase and amylase during treatment with ALUNBRIG. Withhold ALUNBRIG for Grade 3 or 4 pancreatic enzyme elevation. Upon resolution or recovery to Grade 1 or baseline, resume ALUNBRIG at the same dose or at a reduced dose.

Hepatotoxicity

In ALTA 1L, aspartate aminotransferase (AST) elevations occurred in 72% of patients and Grade 3 or 4 AST elevations occurred in 4.5% of patients who received ALUNBRIG. Alanine aminotransferase (ALT) elevations occurred in 52% of patients and Grade 3 or 4 ALT elevations occurred in 5.2% of patients. One patient (0.7%) had a serious adverse reaction of hepatocellular injury.

Please see Important Safety Information on pages 4 to 5 and accompanying full Prescribing Information.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

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Hepatotoxicity (Cont'd)

Monitor AST, ALT and total bilirubin during treatment with ALUNBRIG, especially during the first 3 months. Withhold ALUNBRIG for Grade 3 or 4 hepatic enzyme elevation with bilirubin less than or equal to 2 × ULN. Upon resolution or recovery to Grade 1 or less (less than or equal to 3 × ULN) or to baseline, resume ALUNBRIG at a next lower dose. Permanently discontinue ALUNBRIG for Grade 2 to 4 hepatic enzyme elevation with concurrent total bilirubin elevation greater than 2 times the ULN in the absence of cholestasis or hemolysis.

Hyperglycemia

In ALTA 1L, 56% of patients who received ALUNBRIG experienced new or worsening hyperglycemia. Grade 3 hyperglycemia, based on laboratory assessment of serum fasting glucose levels, occurred in 7.5% of patients. In the ALTA study, 2 of 20 (10%) patients with diabetes or glucose intolerance at baseline required initiation of insulin while receiving ALUNBRIG. Assess fasting serum glucose prior to initiation of ALUNBRIG and monitor periodically thereafter. Initiate or optimize anti-hyperglycemic medications as needed. If adequate hyperglycemic control cannot be achieved with optimal medical management, withhold ALUNBRIG until adequate hyperglycemic control is achieved and consider reducing the dose of ALUNBRIG.

Photosensitivity

In ALTA 1L, 3.7% of patients who received ALUNBRIG experienced photosensitivity, with 0.7% of patients experiencing Grade 3 to 4 reactions. Advise patients to limit sun exposure while taking ALUNBRIG, and for at least 5 days after discontinuation of treatment. Advise patients, when outdoors, to wear protective clothing, and use a broad-spectrum sunscreen and (SPF ≥30) to help protect against sunburn. Based on the severity, withhold ALUNBRIG, then resume at the same dose, or reduce the dose, or permanently discontinue.

Embryo-Fetal Toxicity

Based on its mechanism of action and findings in animals, ALUNBRIG can cause fetal harm when administered to pregnant women. There are no clinical data on the use of ALUNBRIG in pregnant women. Advise women of the potential risk to a fetus.

ADVERSE REACTIONS

The most common adverse reactions (≥25%) with ALUNBRIG were diarrhea, fatigue, nausea, rash, cough, myalgia, headache, hypertension, vomiting, and dyspnea.

DRUG INTERACTIONS

CYP3A Inhibitors: Avoid coadministration of ALUNBRIG with strong or moderate CYP3A inhibitors. If coadministration of a strong or moderate CYP3A inhibitor is unavoidable, reduce the dose of ALUNBRIG.

CYP3A Inducers: Avoid coadministration of ALUNBRIG with strong or moderate CYP3A inducers. If coadministration of a moderate CYP3A inducer is unavoidable, increase the dose of ALUNBRIG.

USE IN SPECIFIC POPULATIONS

Females and Males of Reproductive Potential

Verify pregnancy status in females of reproductive potential prior to initiating ALUNBRIG. Advise females of reproductive potential to use effective contraception during treatment with ALUNBRIG and for at least 4 months after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with ALUNBRIG and for at least 3 months after the final dose. ALUNBRIG may cause reduced fertility in males.

Lactation: Advise patients not to breastfeed.

Hepatic Impairment: Reduce the dose of ALUNBRIG for patients with severe hepatic impairment.

Renal Impairment: Reduce the dose of ALUNBRIG for patients with severe renal impairment.

To report SUSPECTED ADVERSE REACTIONS, contact Takeda Pharmaceuticals U.S.A., Inc. at 1-844-217-6468 or the FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

Please see full Prescribing Information.

Reference: Alunbrig. Prescribing Information. Takeda Pharmaceuticals U.S.A., Inc.; August 2024.

ONCOLOGY

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