ALUNBRIG® (brigatinib) Dosing Guide

INDICATION

ALUNBRIG® (brigatinib) is 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.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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 ALTA, ILD/pneumonitis occurred in 3.7% of patients in the 90 mg group (90 mg once daily) and 9.1% of patients in the 90⟶180 mg group (180 mg once daily with 7-day lead-in at 90 mg once daily). Adverse reactions consistent with possible ILD/pneumonitis occurred within 9 days of initiation of ALUNBRIG (median onset was 2 days) in 6.4% of patients, with Grade 3 to 4 reactions occurring in 2.7% 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 resume ALUNBRIG with dose reduction according to Table 1 of the full Prescribing Information after recovery to baseline or permanently discontinue ALUNBRIG. Permanently discontinue ALUNBRIG for Grade 3 or 4 ILD/pneumonitis or recurrence of Grade 1 or 2 ILD/pneumonitis.

ALK+, anaplastic lymphoma kinase-positive; FDA, Food and Drug Administration; NSCLC, non-small cell lung cancer.

Please see ALUNBRIG Important Safety Information throughout and accompanying full Prescribing Information.

ALUNBRIG®
BRIGATINIB
180mg | 90mg | 30mg
TABLETS

ALUNBRIG® (brigatinib) once-daily dosing regimen

ALUNBRIG has a one-tablet, once-daily recommended dosage that can be taken with or without food

The recommended dosage for ALUNBRIG is 90 mg orally once daily for the first 7 days; then increase the dose to 180 mg orally once daily.

WARNINGS AND PRECAUTIONS (continued)

Hypertension

In ALTA 1L, hypertension was reported in 32% of patients receiving ALUNBRIG; 13% of patients experienced Grade 3 hypertension. In ALTA, hypertension was reported in 11% of patients in the 90 mg group and 21% of patients in the 90⟶180 mg group. Grade 3 hypertension occurred in 5.9% of patients overall. Control blood pressure prior to treatment with ALUNBRIG. Monitor blood pressure after 2 weeks and at least monthly thereafter during treatment with ALUNBRIG. Withhold ALUNBRIG for Grade 3 hypertension despite optimal antihypertensive therapy. Upon resolution or improvement to Grade 1, resume ALUNBRIG at the same dose. 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.

Please see ALUNBRIG Important Safety Information throughout and accompanying full Prescribing Information.

Additional dosage recommendations for ALUNBRIG

- Administer ALUNBRIG until disease progression or unacceptable toxicity
- If ALUNBRIG is interrupted for 14 days or longer for reasons other than adverse reactions, resume treatment at 90 mg once daily for 7 days before increasing to the previously tolerated dose
- ALUNBRIG tablets should be swallowed whole. Do not crush or chew tablets. If a dose of ALUNBRIG is missed or vomiting occurs after taking a dose, do not administer an additional dose. Take next dose at the scheduled time
- Recommendations for dosage modifications of ALUNBRIG for the management of adverse reactions are provided on pages 4 through 11
- Advise your patients to avoid grapefruit or grapefruit juice as it may increase plasma concentrations of ALUNBRIG

Patient Selection

- Select patients for the treatment of metastatic NSCLC with ALUNBRIG based on the presence of ALK positivity in tumor specimens
- Information on FDA-approved tests for the detection of ALK rearrangements in NSCLC is available at **http://www.fda.gov/CompanionDiagnostics**

WARNINGS AND PRECAUTIONS (continued)

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. In ALTA, heart rates less than 50 beats per minute (bpm) occurred in 5.7% of patients in the 90 mg group and 7.6% of patients in the 90⟶180 mg group. One patient (0.9%) in the 90 mg group experienced Grade 2 bradycardia. Monitor heart rate and blood pressure during treatment with ALUNBRIG. Monitor patients more frequently if concomitant use of drug known to cause bradycardia cannot be avoided. For symptomatic bradycardia, withhold ALUNBRIG and review concomitant medications for those known to cause bradycardia. If a concomitant medication known to cause bradycardia is identified and discontinued or dose adjusted, resume ALUNBRIG at the same dose following resolution of symptomatic bradycardia; otherwise, reduce the dose of ALUNBRIG following resolution of symptomatic bradycardia. 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 ALTA, adverse

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180mg | 90mg | 30mg
TABLETS

Recommended dosage modifications for adverse reactions

Dosage-Reduction Levels

FOR 90 MG ONCE DAILY (STARTING DOSE)	FOR 180 MG ONCE DAILY
1st Reduce to 60 mg once daily	1st Reduce to 120 mg once daily
2nd Permanently discontinue	2nd Reduce to 90 mg once daily
	3rd Reduce to 60 mg once daily

- Once reduced for adverse reactions, do not subsequently increase the dosage of ALUNBRIG® (brigatinib)
- Permanently discontinue ALUNBRIG if patients are unable to tolerate the 60 mg once daily dose

Avoid coadministration of strong or moderate CYP3A inhibitors during treatment with ALUNBRIG

- If coadministration of a strong CYP3A inhibitor cannot be avoided, reduce the ALUNBRIG once daily dose by approximately 50% (ie, from 180 mg to 90 mg, or from 90 mg to 60 mg)
- If coadministration of a moderate CYP3A inhibitor cannot be avoided, reduce the ALUNBRIG once daily dose by approximately 40% (ie, from 180 mg to 120 mg, 120 mg to 90 mg, or from 90 mg to 60 mg)
- After discontinuation of a strong or moderate CYP3A inhibitor, resume the ALUNBRIG dose that was tolerated prior to initiating the CYP3A inhibitor

WARNINGS AND PRECAUTIONS (continued)

Visual Disturbance (continued)

reactions leading to visual disturbance, including blurred vision, diplopia, and reduced visual acuity, were reported in 7.3% of patients treated with ALUNBRIG in the 90 mg group and 10% of patients in the 90⟶180 mg group. Grade 3 macular edema and cataract occurred in one patient each in the 90⟶180 mg group. 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 of Grade 2 or Grade 3 visual disturbances to Grade 1 severity or baseline, resume ALUNBRIG at a reduced dose. 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. In ALTA, CPK elevation occurred in 27% of patients receiving ALUNBRIG in the 90 mg group and 48% of patients in the 90⟶180 mg

Please see ALUNBRIG Important Safety Information throughout and accompanying full Prescribing Information.

Avoid coadministration of moderate CYP3A inducers during treatment with ALUNBRIG

- If coadministration of a moderate CYP3A inducer cannot be avoided, increase the ALUNBRIG once daily dose in 30 mg increments after 7 days of treatment with the current ALUNBRIG dose as tolerated, up to a maximum of twice the ALUNBRIG dose that was tolerated prior to initiating the moderate CYP3A inducer
- After discontinuation of a moderate CYP3A inducer, resume the ALUNBRIG dose that was tolerated prior to initiating the moderate CYP3A inducer

For patients with severe hepatic impairment, reduce the ALUNBRIG once daily dose by approximately 40% (ie, from 180 mg to 120 mg, 120 mg to 90 mg, or from 90 mg to 60 mg) for patients with severe hepatic impairment (Child-Pugh C).

For patients with severe renal impairment, reduce the ALUNBRIG once daily dose by approximately 50% (ie, from 180 mg to 90 mg, or from 90 mg to 60 mg) for patients with severe renal impairment [creatinine clearance (CLcr) 15 to 29 mL/min by Cockcroft-Gault].

WARNINGS AND PRECAUTIONS (continued)

Creatine Phosphokinase (CPK) Elevation (continued)

group. The incidence of Grade 3 to 4 CPK elevation was 2.8% in the 90 mg group and 12% in the 90⟶180 mg group. Dose reduction for CPK elevation occurred in 1.8% of patients in the 90 mg group and 4.5% of patients in the 90⟶180 mg group. 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 per Table 2 of the full Prescribing Information.

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. In ALTA, amylase elevation occurred in 27% of patients in the 90 mg group and 39% of patients in the 90⟶180 mg group. Lipase elevations occurred in 21% of patients in the 90 mg group and 45% of patients in the 90⟶180 mg group. Grade 3 or 4 amylase elevation occurred in 3.7% of patients in the 90 mg group and 2.7% of patients in the 90⟶180 mg group. Grade 3 or 4 lipase elevation occurred in 4.6% of patients in the 90 mg group and 5.5% of patients in the 90⟶180 mg group. Monitor lipase and amylase during treatment with ALUNBRIG. Withhold ALUNBRIG for Grade 3 or 4 pancreatic enzyme elevation. Upon resolution or

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TABLETS

Recommended dosage modifications for adverse reactions (continued)

Adverse Reaction and Severity[a]

INTERSTITIAL LUNG DISEASE/PNEUMONITIS | GRADE 1

- If new pulmonary symptoms occur during the first 7 days of treatment, withhold ALUNBRIG® (brigatinib) until recovery to baseline, then resume at same dose and do not escalate to 180 mg if ILD/pneumonitis is suspected.
- If new pulmonary symptoms occur after the first 7 days of treatment, withhold ALUNBRIG until recovery to baseline, then resume at same dose.
- If ILD/pneumonitis recurs, permanently discontinue ALUNBRIG.

INTERSTITIAL LUNG DISEASE/PNEUMONITIS | GRADE 2

- If new pulmonary symptoms occur during the first 7 days of treatment, withhold ALUNBRIG until recovery to baseline. Resume at next lower dose as described on page 4 and do not escalate if ILD/pneumonitis is suspected.
- If new pulmonary symptoms occur after the first 7 days of treatment, withhold ALUNBRIG until recovery to baseline. If ILD/pneumonitis is suspected, resume at next lower dose as described on page 4; otherwise, resume at the same dose.
- If ILD/pneumonitis recurs, permanently discontinue ALUNBRIG.

WARNINGS AND PRECAUTIONS (continued)

Pancreatic Enzyme Elevation (continued)

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. In ALTA, AST elevations occurred in 38% of patients in the 90 mg group and 65% of patients in the 90⟶180 mg group. ALT elevations occurred in 34% of patients in the 90 mg group and 40% of patients in the 90⟶180 mg group. Grade 3 or 4 AST elevations occurred in 0.9% of patients in the 90 mg group and did not occur in any patients in the 90⟶180 mg group. Grade 3 or 4 ALT elevations did not occur in any patients in the 90 mg group and in 2.7% of patients in the 90⟶180 mg group. 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

Please see ALUNBRIG Important Safety Information throughout and accompanying full Prescribing Information.

INTERSTITIAL LUNG DISEASE/PNEUMONITIS | GRADE 3 OR 4

Permanently discontinue ALUNBRIG for ILD/pneumonitis.

HYPERTENSION | GRADE 3

(SBP ≥160 mmHg or DBP ≥100 mmHg, medical intervention indicated, more than one antihypertensive drug, or more intensive therapy than previously used indicated)

- Withhold ALUNBRIG until recovery to ≤Grade 1 (SBP <140 mmHg and DBP <90 mmHg), then resume ALUNBRIG at the same dose.
- Recurrence: Withhold ALUNBRIG until recovery to ≤Grade 1, and resume at next lower dose as per page 4 or permanently discontinue treatment.

HYPERTENSION | GRADE 4

(Life-threatening consequences, urgent intervention indicated)

- Withhold ALUNBRIG until recovery to ≤Grade 1, and resume at the next lower dose as per page 4 or permanently discontinue treatment.
- Recurrence: Permanently discontinue ALUNBRIG for recurrence of Grade 4 hypertension.

[a]Graded per National Cancer Institute Common Terminology Criteria for Adverse Events. Version 4.0 (NCI CTCAE v4.0).

DBP, diastolic blood pressure; SBP, systolic blood pressure.

WARNINGS AND PRECAUTIONS (continued)

Hepatotoxicity (continued)

per Table 2 of the full Prescribing Information. 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 ALTA, 43% of patients who received ALUNBRIG experienced new or worsening hyperglycemia. Grade 3 hyperglycemia, based on laboratory assessment of serum fasting glucose levels, occurred in 3.7% of patients. Two 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

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180mg | 90mg | 30mg
TABLETS

Recommended dosage modifications for adverse reactions (continued)

Adverse Reaction and Severity[a]
BRADYCARDIA (HEART RATE <60 BPM) Symptomatic bradycardia • Withhold ALUNBRIG® (brigatinib) until recovery to asymptomatic bradycardia or to a resting heart rate of 60 bpm or above. • If a concomitant medication known to cause bradycardia is identified and discontinued or dose adjusted, resume ALUNBRIG at same dose upon recovery to asymptomatic bradycardia or to resting heart rate of 60 bpm or above. • If no concomitant medication known to cause bradycardia is identified, or if contributing concomitant medications are not discontinued or dose adjusted, resume ALUNBRIG at next lower dose per page 4 upon recovery to asymptomatic bradycardia or to resting heart rate of 60 bpm or above.
BRADYCARDIA (HEART RATE <60 BPM) Bradycardia with life-threatening consequences, urgent intervention indicated • Permanently discontinue ALUNBRIG if no contributing concomitant medication is identified. • If contributing concomitant medication is identified and discontinued or dose adjusted, resume ALUNBRIG at next lower dose per page 4 upon recovery to asymptomatic bradycardia or to a resting heart rate of 60 bpm or above, with frequent monitoring as clinically indicated. • Recurrence: Permanently discontinue ALUNBRIG.

bpm, beats per minute.

WARNINGS AND PRECAUTIONS (continued)

Hyperglycemia (continued)

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 dosage per Table 1 of the full Prescribing Information or permanently discontinuing 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. In ALTA, 0.9% of patients who received ALUNBRIG in the 90 mg group and 0.9% of patients in the 90⟶180 mg group experienced photosensitivity. Grade 3 to 4 photosensitivity was not reported in patients in the 90 mg group or in the 90⟶180 mg group. Advise patients to limit sun exposure

Please see ALUNBRIG Important Safety Information throughout and accompanying full Prescribing Information.

Adverse Reaction and Severity[a]
VISUAL DISTURBANCE | GRADE 2 OR 3 Withhold ALUNBRIG until recovery to Grade 1 or baseline, then resume at the next lower dose per page 4.
VISUAL DISTURBANCE | GRADE 4 Permanently discontinue ALUNBRIG.

[a]Graded per NCI CTCAE v4.0.

WARNINGS AND PRECAUTIONS (continued)

Photosensitivity (continued)

while taking ALUNBRIG, and for at least 5 days after discontinuation of treatment. Advise patients, when outdoors, to wear a hat and protective clothing, and use a broad-spectrum Ultraviolet A (UVA)/Ultraviolet B (UVB) sunscreen and lip balm (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. Advise females of reproductive potential to use effective contraception during treatment with ALUNBRIG and for at least 4 months following the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment and for at least 3 months after the last dose of ALUNBRIG.

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.

ALUNBRIG®
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180mg | 90mg | 30mg
TABLETS

Recommended dosage modifications for adverse reactions (continued)

Adverse Reaction and Severity[a]

CREATINE PHOSPHOKINASE ELEVATION

GRADE 3 OR 4 CPK ELEVATION (GREATER THAN 5 × ULN) WITH GRADE 2 OR HIGHER MUSCLE PAIN OR WEAKNESS

- Withhold ALUNBRIG® (brigatinib) until recovery to ≤Grade 1 (≤2.5 × ULN) CPK elevation or to baseline, then resume ALUNBRIG at same dose.
- Recurrence: Withhold ALUNBRIG until recovery to ≤Grade 1 (≤2.5 × ULN) CPK elevation or to baseline, then resume ALUNBRIG at the next lower dose per page 4.

LIPASE/AMYLASE ELEVATION | GRADE 3

Lipase or amylase elevation (>2 × ULN)

- Withhold ALUNBRIG until recovery to ≤Grade 1 (≤1.5 × ULN) or to baseline, then resume ALUNBRIG at same dose.
- Recurrence: Withhold ALUNBRIG until recovery to ≤Grade 1 (≤1.5 × ULN) or to baseline, then resume ALUNBRIG at next lower dose per page 4.

LIPASE/AMYLASE ELEVATION | GRADE 4

Lipase or amylase elevation (>5 × ULN)

- Withhold ALUNBRIG until recovery to ≤Grade 1 (≤1.5 × ULN) or to baseline, then resume ALUNBRIG at next lower dose per page 4.

HEPATOTOXICITY (ELEVATION OF ALANINE AMINOTRANSFERASE [ALT] OR ASPARTATE AMINOTRANSFERASE [AST]) | GRADE 3 OR 4

Elevation (>5 × ULN) of either ALT or AST with bilirubin ≤2 × ULN

- Withhold ALUNBRIG until recovery to ≤Grade 1 (≤3 × ULN) or to baseline, then resume ALUNBRIG at next lower dose per page 6.

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.

Please see ALUNBRIG Important Safety Information throughout and accompanying full Prescribing Information.

HEPATOTOXICITY (ELEVATION OF ALT OR AST) | GRADE 2 TO 4

Elevation (>3 × ULN) of ALT or AST with concurrent total bilirubin elevation >2 × ULN in the absence of cholestasis or hemolysis

- Permanently discontinue ALUNBRIG.

HYPERGLYCEMIA | GRADE 3

(>250 mg/dL or 13.9 mmol/L) OR 4

- If adequate hyperglycemic control cannot be achieved with optimal medical management, withhold ALUNBRIG until adequate hyperglycemic control is achieved and resume at the next lower dose per page 4 or permanently discontinue ALUNBRIG.

OTHER | GRADE 3

- Withhold ALUNBRIG until recovery to baseline, then resume at the same dose.
- Recurrence: Withhold ALUNBRIG until recovery to baseline, then resume at the lower dose or discontinue ALUNBRIG as per page 4.

OTHER | GRADE 4

- Withhold ALUNBRIG until recovery to baseline and resume at the next lower dose as per page 4.
- Recurrence: Permanently discontinue ALUNBRIG.

[a]Graded per NCI CTCAE v4.0.
ULN, upper limit of normal.

USE IN SPECIFIC POPULATIONS (continued)

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.

ALUNBRIG®
BRIGATINIB
180mg | 90mg | 30mg
TABLETS

ALUNBRIG® (brigatinib) has a **one-tablet, once-daily** recommended dosing regimen that can be taken **with or without food**.

GET PATIENTS STARTED ON ALUNBRIG

To assist patients who are starting on ALUNBRIG, the first-month supply of the recommended dosing regimen is available in an **Initiation Pack** that contains one bottle of 90 mg tablets (7 count) and one bottle of 180 mg tablets (23 count).

Visit **ALUNBRIG.com/hcp** to learn more.

DOSAGE FORMS AND STORAGE

- ALUNBRIG is available in:
  - 180-mg tablets: oval, white to off-white film-coated tablet with "U13" debossed on one side and plain on the other side
  - 90-mg tablets: oval, white to off-white film-coated tablet with "U7" debossed on one side and plain on the other side
  - 30-mg tablets: round, white to off-white film-coated tablet with "U3" debossed on one side and plain on the other side
- Store at controlled room temperature 68°F to 77°F (20°C to 25°C).

CONTACT US WITH ANY QUESTIONS

To report an adverse event or product complaint, please call:

1-844-217-6468 or FDA at 1-800-FDA-1088
or **www.fda.gov/medwatch**

Please see the accompanying full Prescribing Information.

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TABLETS