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 the ALUNBRIG arm of trial ALTA 1L (180 mg once daily), 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 Trial 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 early 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%. Monitor for new or worsening respiratory symptoms (e.g., 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 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.

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)

Hypertension: In the ALUNBRIG arm of trial ALTA 1L (180 mg once daily), hypertension was reported in 32% of patients receiving ALUNBRIG; Grade 3 hypertension occurred in 13% of patients. In ALTA, hypertension was reported in 11% of patients in the 90 mg group who received ALUNBRIG 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.

WARNINGS AND PRECAUTIONS (continued)

Bradycardia: In the ALUNBRIG arm of trial ALTA 1L (180 mg once daily), heart rates less than 50 beats per minute (bpm) occurred in 8.1% of patients receiving ALUNBRIG. Grade 3 bradycardia occurred in 1 patient (0.7%). 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. Grade 2 bradycardia occurred in 1 (0.9%) patient in the 90 mg group. 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.

ALUNBRIG®
BRIGATINIB
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: In the ALUNBRIG arm of trial ALTA 1L (180 mg once daily), 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 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.

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: In the ALUNBRIG arm of trial ALTA 1L (180 mg once daily), 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 group. The incidence of Grade 3-4 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% 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.

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

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)

Pancreatic Enzyme Elevation: In the ALUNBRIG arm of trial ALTA 1L (180 mg once daily), amylase elevation occurred in 52% of patients and Grade 3 or 4 amylase elevation occurred in 6.8% of patients. 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 recovery to Grade 1 or baseline, resume ALUNBRIG at the same dose or at a reduced dose.

WARNINGS AND PRECAUTIONS (continued)

Hyperglycemia: In the ALUNBRIG arm of trial ALTA 1L (180 mg once daily), 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 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 or permanently discontinuing ALUNBRIG.

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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)

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 pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective non-hormonal 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.

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

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.

ADVERSE REACTIONS

In ALTA 1L, serious adverse reactions occurred in 33% of patients receiving ALUNBRIG. The most common serious adverse reactions were pneumonia (4.4%), ILD/pneumonitis (3.7%), pyrexia (2.9%), dyspnea (2.2%), pulmonary embolism (2.2%), and asthenia (2.2%). Fatal adverse reactions occurred in 2.9% of patients and included pneumonia (1.5%), cerebrovascular accident (0.7%), and multiple organ dysfunction syndrome (0.7%).

In ALTA, serious adverse reactions occurred in 38% of patients in the 90 mg group and 40% of patients in the 90⟶180 mg group. The most common serious adverse reactions were pneumonia (5.5% overall, 3.7% in the 90 mg group, and 7.3% in the 90⟶180 mg group) and ILD/pneumonitis (4.6% overall, 1.8% in the 90 mg group and 7.3% in the 90⟶180 mg group). Fatal adverse reactions occurred in 3.7% of patients and consisted of pneumonia (2 patients), sudden death, dyspnea, respiratory failure, pulmonary embolism, bacterial meningitis and urosepsis (1 patient each).

The most common adverse reactions (≥25%) with ALUNBRIG were diarrhea (49%), fatigue (39%), nausea (39%), rash (38%), cough (37%), myalgia (34%), headache (31%), hypertension (31%), vomiting (27%), and dyspnea (26%).

DRUG INTERACTIONS

CYP3A Inhibitors: Avoid coadministration of ALUNBRIG with strong or moderate CYP3A inhibitors. Avoid grapefruit or grapefruit juice as it may also increase plasma concentrations of brigatinib. If coadministration of a strong or moderate CYP3A inhibitor cannot be avoided, reduce the dose of ALUNBRIG.

CYP3A Inducers: Avoid coadministration of ALUNBRIG with strong or moderate CYP3A inducers. If coadministration of moderate CYP3A inducers cannot be avoided, increase the dose of ALUNBRIG.

CYP3A Substrates: Coadministration of ALUNBRIG with sensitive CYP3A substrates, including hormonal contraceptives, can result in decreased concentrations and loss of efficacy of sensitive CYP3A substrates.

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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.

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

Pregnancy: ALUNBRIG can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus.

Lactation: There are no data regarding the secretion of brigatinib in human milk or its effects on the breastfed infant or milk production. Because of the potential adverse reactions in breastfed infants, advise lactating women not to breastfeed during treatment with ALUNBRIG.

Females and Males of Reproductive Potential:

Pregnancy Testing: Verify pregnancy status in females of reproductive potential prior to initiating ALUNBRIG.

Contraception: Advise females of reproductive potential to use effective non-hormonal 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.

Infertility: ALUNBRIG may cause reduced fertility in males.

USE IN SPECIFIC POPULATIONS (continued)

Pediatric Use: The safety and effectiveness of ALUNBRIG in pediatric patients have not been established.

Geriatric Use: Of the 359 patients enrolled in the ALTA 1L ALUNBRIG arm and in ALTA, 26.7% were 65 and older and 7.5% were 75 and older. No clinically relevant differences in safety or efficacy were observed between patients ≥65 years and younger patients.

Hepatic or Renal Impairment: No dose adjustment is recommended for patients with mild or moderate hepatic impairment or mild or moderate renal impairment. Reduce the dose of ALUNBRIG for patients with severe hepatic impairment or severe renal impairment.

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

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:

1-844-817-6468 or FDA at 1-800-FDA-1088
or **www.fda.gov/medwatch**

Please see the accompanying full Prescribing Information.

Takeda | ONCOLOGY

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TABLETS