ALUNBRIG (brigatinib) is indicated as monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK) positive advanced non-small cell lung cancer (aNSCLC) who:

Have not previously been treated with an ALK inhibitor[1]

Or

Have previously received crizotinib treatment.[1]

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

MANAGING DOSE MODIFICATIONS WITH ALUNBRIG

A GUIDE FOR HEALTHCARE PROFESSIONALS

Please refer to the Summary of Product Characteristics for full prescribing and monitoring guidance[1]

Prescribing information and adverse event reporting can be found at the end of the document

This guide is intended for healthcare professionals practicing in the Republic of Ireland.

C-APROM/IE/ALUN/0131
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Takeda | ONCOLOGY

CONTENTS

OVERVIEW 3
RECOMMENDED DOSING 4
DOSING MODIFICATIONS 8
ILD/ PNEUMONITIS 8
HYPERTENSION 9
BRADYCARDIA 10
ELEVATION OF CPK & ELEVATION OF LIPASE/AMYLASE 11
HEPATOTOXICITY & HYPERGLYCAEMIA 12
VISUAL DISTURBANCE & OTHER ADVERSE REACTIONS 13
TAKING ALUNBRIG 14
PI 17

See ALK+ aNSCLC, **Think** Brain Metastases, **Choose** ALUNBRIG (brigatinib)

For both intracranial and extracranial efficacy[2]



Up to 75% of ALK+ aNSCLC patients will develop brain metastases during their disease.[3-5]

Patients need a treatment that delivers both intracranial and extracranial efficacy.

ALTA-1L: ALUNBRIG demonstrated superior systemic and intracranial median progression free survival (mPFS) vs crizotinib[2]

- Halved the risk of disease progression or death vs crizotinib in ITT population (BIRC-assessed mPFS of **24.0 months** with ALUNBRIG vs **11.1 months** with crizotinib, **HR=0.48;** *P*<0.0001)[2]
- Over two thirds reduction in risk of intracranial disease progression or death in patients with any brain metastases at baseline (BIRC-assessed intracranial mPFS of **24.0 months** with ALUNBRIG vs **5.5 months** with crizotinib, **HR=0.29;** *P*<0.0001)[2]

ALUNBRIG has demonstrated a consistent tolerability profile

- In the ALTA-1L study, the most common (>25%) AEs of any grade included gastrointestinal events, increased blood CPK, cough, and increased aminotransferases[2]



ALTA-1L: ALUNBRIG demonstrated HRQOL benefit vs crizotinib[2,6]

- Median time to worsening was 26.7 months for ALUNBRIG vs **8.3 months** for crizotinib (HR=0.69, 95% CI: 0.49–0.98; *P*=0.047)[2]
- Median duration of improvement in GHS/QOL **not reached** with ALUNBRIG vs **12 months** for crizotinib (**HR=0.27;** *P*<0.0001) [a,6]

INDICATIONS[1]

- ALUNBRIG is indicated as monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously not treated with an ALK inhibitor
- ALUNBRIG is indicated as monotherapy for the treatment of adult patients with ALK-positive advanced NSCLC previously treated with crizotinib

[a]As reported at the 2nd interim analysis of the ALTA-1L trial (data cut-off June 28, 2019). All other results are from the final analysis (data cut-off January 29, 2021).

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

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ALUNBRIG HAS A ONCE DAILY RECOMMENDED DOSING REGIMEN THAT CAN BE TAKEN WITH OR WITHOUT FOOD[1]

WEEK 1
DAYS 1–7
90 MG ONCE DAILY

IF TOLERATED

- Crizotinib should be discontinued **at least 7 days** before initiating ALUNBRIG, as shorter washout periods have been associated with an increased incidence of pulmonary adverse events[1,7]
- The recommended starting dose of ALUNBRIG is **90 mg** once daily for the first 7 days, then if tolerated increased to **180 mg** once daily[1]
- A reduced starting dose of **60 mg** once daily for the first 7 days, then **120 mg** once daily is recommended for patients with **severe hepatic impairment** (Child-Pugh class C)[1]
- A reduced starting dose of **60 mg** once daily for the first 7 days, then **90 mg** once daily is recommended for patients with **severe renal impairment** (eGFR <30 mL/min)[1]

WEEK 2+
DAY 8 AND BEYOND
180 MG ONCE DAILY

- **If ALUNBRIG is interrupted** for 14 days or longer for reasons other than adverse reactions, treatment should be resumed at **90 mg** once daily for 7 days before increasing to the previously tolerated dose[1]
- If a dose is missed or vomiting occurs after taking a dose, an additional dose should **not** be administered and the next dose should be taken at the scheduled time[1]
- Treatment should continue **as long as clinical benefit is observed**[1]



ALUNBRIG is available in 180 mg, 90 mg and 30 mg tablets

A starter pack for ALUNBRIG is available for patients and their clinical team to manage the first month on treatment.

The pack contains two colour coded blister pack inserts:

- **The first insert (colour coded blue)** contains 7 x 90 mg tablets, clearly labelled for Days 1–7
- **The second insert (colour coded green)** contains 21 x 180 mg tablets, clearly labelled for Days 8–28



ALUNBRIG RECOMMENDED DOSE MODIFICATIONS FOR ADVERSE REACTIONS[1]

FOR **90 MG** ONCE DAILY (RECOMMENDED STARTING DOSE)

1st	Reduce to 60 mg once daily
2nd	Permanently discontinue

- If patients cannot tolerate the 60 mg once daily dose, **discontinue** ALUNBRIG permanently[1]

FOR **180 MG** ONCE DAILY

1st	Reduce to 120 mg once daily
2nd	Reduce to 90 mg once daily
3rd	Reduce to 60 mg once daily

- If patients cannot tolerate the 60 mg once daily dose, **discontinue** ALUNBRIG permanently[1]

Grade 1

DOSE MODIFICATION

- If event occurs during the first 7 days of treatment, ALUNBRIG should be withheld until recovery to baseline, then resumed at same dose level and not escalated to 180 mg once daily
- If ILD/pneumonitis occurs after the first 7 days of treatment, ALUNBRIG should be withheld until recovery to baseline, then resumed at same dose level
- If ILD/pneumonitis recurs, ALUNBRIG should be permanently discontinued

Grade 2

DOSE MODIFICATION

- If ILD/pneumonitis occurs during the first 7 days of treatment, ALUNBRIG should be withheld until recovery to baseline, then resumed at next lower dose level* and not escalated to 180 mg once daily
- If ILD/pneumonitis occurs after the first 7 days of treatment, ALUNBRIG should be withheld until recovery to baseline. ALUNBRIG should be resumed at next lower dose level*
- If ILD/pneumonitis recurs, ALUNBRIG should be permanently discontinued

Grade 3 or 4

DOSE MODIFICATION

- ALUNBRIG should be permanently discontinued

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

*Please see pages 6–7 for dose modification information.

Grade 3

Hypertension (SBP ≥160 mmHg or DBP ≥100 mmHg, medical intervention indicated, more than one anti-hypertensive medicinal product, or more intensive therapy than previously used indicated)

DOSE MODIFICATION

- ALUNBRIG should be withheld until hypertension has recovered to Grade ≤1 (SBP <140 mmHg and DBP <90 mmHg), then resumed at same dose
- If Grade 3 hypertension recurs, ALUNBRIG should be withheld until hypertension has recovered to Grade ≤1 then resumed at the next lower dose level* or permanently discontinued

Grade 4

Hypertension (life-threatening consequences, urgent intervention indicated)

DOSE MODIFICATION

- ALUNBRIG should be withheld until hypertension has recovered to Grade ≤1 (SBP <140 mmHg and DBP <90 mmHg), then resumed at the next lower dose level* or permanently discontinued
- If Grade 4 hypertension recurs, ALUNBRIG should be permanently discontinued

*Please see pages 6–7 for dose modification information.

BRADYCARDIA (HEART RATE <60 BPM)

Symptomatic bradycardia

DOSE MODIFICATION

- ALUNBRIG should be withheld until recovery to asymptomatic bradycardia or to a resting heart rate of 60 bpm or above
- If a concomitant medicinal product known to cause bradycardia is identified and discontinued, or its dose is adjusted, ALUNBRIG should be resumed at same dose upon recovery to asymptomatic bradycardia or to a resting heart rate of 60 bpm or above
- If no concomitant medicinal product known to cause bradycardia is identified, or if contributing concomitant medications are not discontinued or dose modified, ALUNBRIG should be resumed at the next lower dose level* upon recovery to asymptomatic bradycardia or to a resting heart rate of 60 bpm or above

Bradycardia with life-threatening consequences, urgent intervention indicated

DOSE MODIFICATION

- If contributing concomitant medicinal product is identified and discontinued, or its dose is adjusted, ALUNBRIG should be resumed at the next lower dose level* upon recovery to asymptomatic bradycardia or to a resting heart rate of 60 bpm or above, with frequent monitoring as clinically indicated
- ALUNBRIG should be permanently discontinued if no contributing concomitant medicinal product is identified
- ALUNBRIG should be permanently discontinued in case of recurrence

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

*Please see pages 6–7 for dose modification information.

ELEVATION OF CPK

Grade ≥3

Elevation of CPK (>5.0 × ULN) with Grade ≥2 muscle pain or weakness

DOSE MODIFICATION

- ALUNBRIG should be withheld until recovery to Grade ≤1 (≤2.5 × ULN) elevation of CPK or to baseline, then resumed at the same dose
- If Grade 3 or 4 elevation of CPK recurs with Grade ≥2 muscle pain or weakness, ALUNBRIG should be withheld until recovery to Grade ≤1 (≤2.5 × ULN) elevation of CPK or to baseline, then resumed at the next lower dose level*

ELEVATION OF LIPASE OR AMYLASE

Grade 3

Elevation of lipase or amylase (>2.0 × ULN)

DOSE MODIFICATION

- ALUNBRIG should be withheld until recovery to Grade ≤1 (≤1.5 × ULN) or to baseline, then resumed at same dose
- If Grade 3 elevation of lipase and amylase recurs, ALUNBRIG should be withheld until recovery to Grade ≤1 (≤1.5 × ULN) or to baseline, then resumed at the next lower dose level*

Grade 4

Elevation of lipase or amylase (>5.0 × ULN)

DOSE MODIFICATION

- ALUNBRIG should be withheld until recovery to Grade ≤1 (≤1.5 × ULN), then resumed at the next lower dose level*

*Please see pages 6–7 for dose modification information.

HEPATOTOXICITY

Grade ≥3 Elevation (>5.0 × ULN) of either alanine aminotransferase (ALT) or aspartate aminotransferase (AST) with bilirubin ≤2 × ULN

DOSE MODIFICATION

- ALUNBRIG should be withheld until recovery to baseline or ≤3 × ULN, then resumed at next lower dose level*

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

DOSE MODIFICATION

- ALUNBRIG should be permanently discontinued

HYPERGLYCAEMIA

Grade ≥3 (>250 mg/dL or 13.9 mmol/L)

DOSE MODIFICATION

- If adequate hyperglycaemic control cannot be achieved with optimal medical management, ALUNBRIG should be withheld until adequate hyperglycaemic control is achieved. Upon recovery, ALUNBRIG may either be resumed at the next lower dose level* or permanently discontinued

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

*Please see pages 6–7 for dose modification information.

VISUAL DISTURBANCE

Grade 2 or 3

DOSE MODIFICATION

- ALUNBRIG should be withheld until recovery to Grade 1 or baseline, then resumed at the next lower dose level*

Grade 4

DOSE MODIFICATION

- ALUNBRIG should be permanently discontinued

OTHER ADVERSE REACTIONS

Grade 3

DOSE MODIFICATION

- ALUNBRIG should be withheld until recovery to baseline, then resumed at the same dose level
- If the Grade 3 event recurs, ALUNBRIG should be withheld until recovery to baseline, then resumed at the next lower dose level* or permanently discontinued

Grade 4

DOSE MODIFICATION

- ALUNBRIG should be withheld until recovery to baseline, then resumed at the next lower dose level*
- If the Grade 4 event recurs, ALUNBRIG should be withheld until recovery to baseline, then resumed at the next lower dose level* or permanently discontinued

*Please see pages 6–7 for dose modification information.

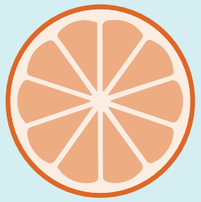
ALUNBRIG MAY BE TAKEN WITH OR WITHOUT FOOD[1]



← 19 mm →
for 180 mg tablet

Tablet not shown at actual size

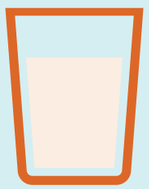
ALUNBRIG should be taken **once daily at the same time each day**



Grapefruit and grapefruit juice should be **avoided** during treatment



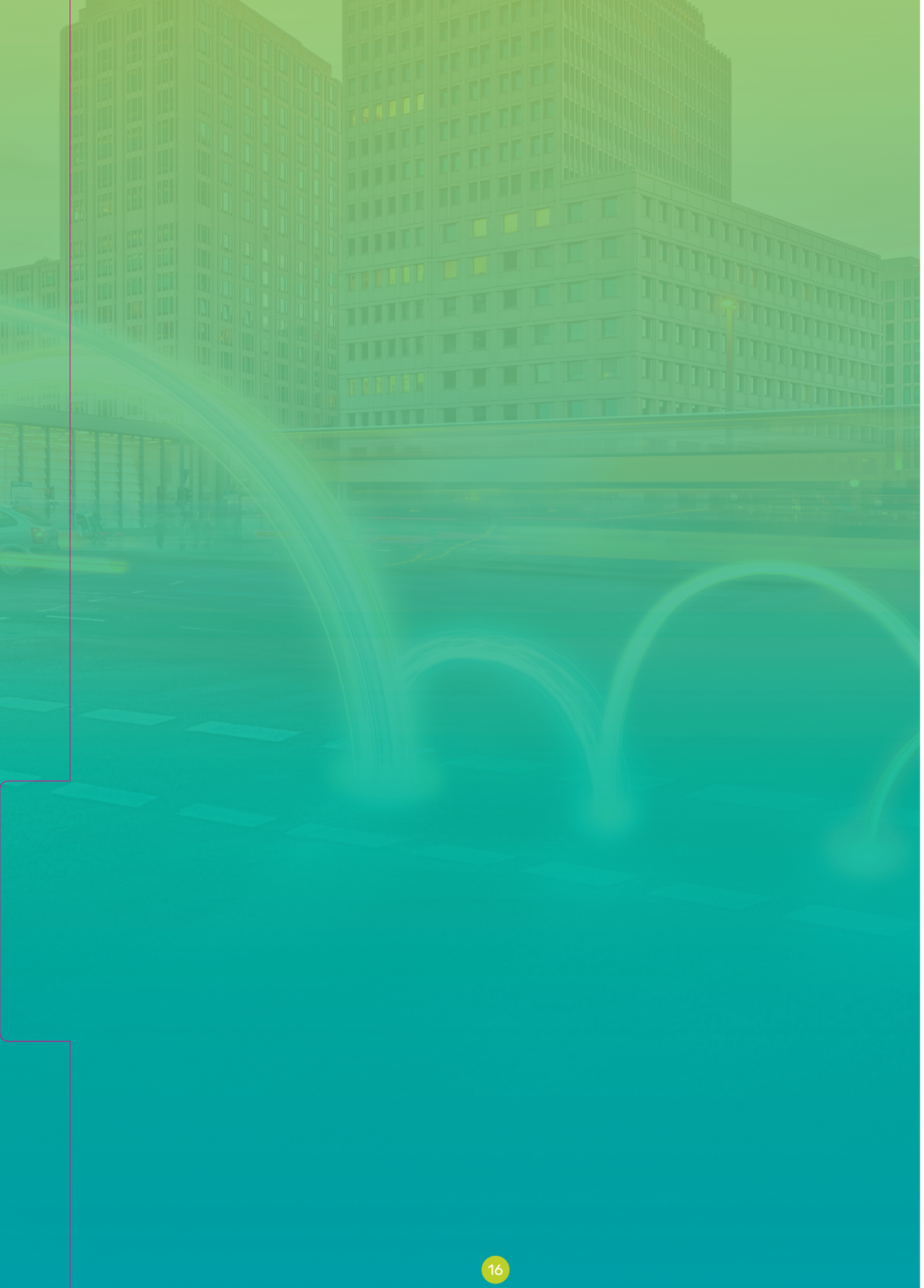
Patients should be advised that if they vomit after taking ALUNBRIG, they **should not take any more** tablets until the next scheduled dose



Tablets should be **swallowed whole and with water**



Please refer to the Summary of Product Characteristics for full prescribing and monitoring guidance.[1]



AE, adverse event; **ALK**, anaplastic lymphoma kinase; **ALK+**, anaplastic lymphoma kinase positive; **ALT**, alanine aminotransferase; **aNSCLC**, advanced non-small cell lung cancer; **AST**, aspartate aminotransferase; **BIRC**, blinded independent review committee; **BPM**, beats per minute; **CPK**, creatine phosphokinase; **DBP**, diastolic blood pressure; **eGFR**, estimated glomerular filtration rate; **GHS**, general health status; **HR**, hazard ratio; **ILD**, interstitial lung disease; **ITT**, intention to treat; **mPFS**, median progression free survival; **QOL**, quality of life; **SBP**, systolic blood pressure; **ULN**, upper limit of normal.

References: 1. Alunbrig Summary of Product Characteristics. Available at: https://www.medicines.ie/medicines/alunbrig-34655/spc Accessed April 2026; **2.** Camidge DR, et al. J Thorac Oncol 2021;16:2091–2108; **3.** Solomon BJ, et al. Lancet Oncol 2018;19:1654–1667; **4.** Descourt R, et al. Lung Cancer 2019;136:109–114; **5.** Huber RM, et al. J Thorac Oncol 2020;15:404–415; **6.** Camidge DR, J Clin Oncol 2020;38:3592–3603; **7.** Kim DW, et al. J Clin Oncol 2017;35:2490–8.

ALUNBRIG® (brigatinib) PRESCRIBING INFORMATION FOR REPUBLIC OF IRELAND

Refer to the Summary of Product Characteristics (SmPC) before prescribing

Presentation: Brigatinib 180 mg, 90 mg and 30 mg film-coated tablets for oral use. **Indications:** As monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously not treated with an ALK inhibitor. As monotherapy for the treatment of adult patients with ALK-positive advanced NSCLC previously treated with crizotinib. **Dosage and administration:** Treatment with ALUNBRIG should be initiated and supervised by a physician experienced in the use of anticancer medicinal products. Recommended starting dose is 90 mg once daily for the first 7 days, then 180 mg once daily. If ALUNBRIG is interrupted for 14 days or longer for reasons other than adverse reactions, treatment should be resumed at 90 mg once daily for 7 days before increasing to the previously tolerated dose. If a dose is missed or vomiting occurs after taking a dose, an additional dose should not be administered and the next dose should be taken at the scheduled time. Treatment should continue as long as clinical benefit is observed. Dosing interruption and/or dose reduction may be required. Refer to SmPC for full dose adjustments. Paediatric population: No data are available. Elderly patients: Dose adjustment is not required. No available data on patients aged > 85 years. Hepatic impairment: A reduced starting dose of 60 mg once daily for the first 7 days, then 120 mg once daily is recommended for patients with severe hepatic impairment (ChildPugh class C). Renal impairment: A reduced starting dose of 60 mg once daily for the first 7 days, then 90 mg once daily is recommended for patients with severe renal impairment (eGFR <30 mL/min). Patients with severe renal impairment should be closely monitored for new or worsening respiratory symptoms (e.g., dyspnoea, cough, etc.) particularly in the first week. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Warnings and precautions:** Refer to SmPC for recommended dose modifications. Pulmonary adverse reactions: Most occurred within the first 7 days of treatment, but they can occur later in treatment. Patients should be monitored for new or worsening respiratory symptoms (e.g., dyspnoea, cough, etc.), particularly in the first week of treatment. If interstitial lung disease/pneumonitis is suspected, the dose of ALUNBRIG should be withheld, and the patient evaluated for other causes of symptoms (e.g., pulmonary embolism, tumour progression, and infectious pneumonia). Dose modification may be required. Hypertension: Heart rate and blood pressure should be monitored regularly. Hypertension should be treated according to standard guidelines. Heart rate should be monitored more frequently in patients if concomitant use of a medicinal product known to cause bradycardia cannot be avoided. Withhold ALUNBRIG in patients with severe hypertension (≥ Grade 3) until hypertension has recovered to Grade 1 or to baseline. Modify dose accordingly. Bradycardia: Caution should be exercised when administering ALUNBRIG in combination with other agents known to cause bradycardia. If symptomatic bradycardia occurs, treatment with ALUNBRIG should be withheld and concomitant medicinal products known to cause bradycardia should be evaluated. Upon recovery, the dose should be modified according to the SmPC. In case of life-threatening bradycardia, if no contributing concomitant medication is identified or in case of recurrence, treatment with ALUNBRIG should be discontinued. Visual disturbance: Advise patients to report any visual symptoms. Consider ophthalmologic evaluation/ dose reduction for new or worsening severe symptoms. Creatine phosphokinase (CPK) elevation: Patients should be advised to report any unexplained muscle pain, tenderness, or weakness. CPK levels should be monitored regularly during ALUNBRIG treatment. Based on the severity of the CPK elevation, and if associated with muscle pain or weakness, treatment with ALUNBRIG should be withheld, and the dose modified. Elevations of pancreatic enzymes: Lipase and amylase should be monitored regularly during treatment with ALUNBRIG. Based on the severity of the laboratory abnormalities, treatment with ALUNBRIG should be withheld, and the dose modified. Hepatotoxicity: Liver function, including aspartate aminotransferase (AST), alanine aminotransferase (ALT) and total bilirubin should be assessed prior to the initiation of ALUNBRIG and then every 2 weeks during the first 3 months of treatment. Thereafter, monitoring should be performed periodically. Based on the severity of the laboratory abnormalities, treatment should be withheld, and the dose modified. Hyperglycaemia: Fasting serum glucose should be assessed prior to initiation of ALUNBRIG and monitored periodically thereafter. Antihyperglycaemic medications should be initiated or optimised as needed. If adequate hyperglycaemic control cannot be achieved with optimal medical management, ALUNBRIG should be withheld until adequate hyperglycaemic control is achieved; upon recovery, dose reduce ALUNBRIG as per the SmPC or permanent discontinuation may be considered. Photosensitivity and photodermatosis: Photosensitivity to sunlight has occurred in patients treated with ALUNBRIG. Patients should be advised to avoid prolonged sun exposure while taking ALUNBRIG and for at least 5 days after discontinuation of treatment. When outdoors, advise patients to wear a hat and protective clothing and to use a broad-spectrum Ultraviolet A/B sunscreen and lip balm (SPF≥30). For severe photosensitivity reactions (≥Grade 3) withhold ALUNBRIG until recovery to baseline. The dose should be modified accordingly. Lactose: ALUNBRIG contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency, or glucose-galactose malabsorption should not take ALUNBRIG. Sodium: ALUNBRIG is essentially 'sodium-free' containing less than 1 mmol sodium (23 mg) per tablet. **Interactions:** Avoid use with strong CYP3A inhibitors. Avoid use with strong and moderate CYP3A inducers. Please refer to the SmPC for further information and guidance for situations where use cannot be avoided. Grapefruit or grapefruit juice should be avoided. Coadministration of ALUNBRIG with CYP3A substrates with a narrow therapeutic index should be avoided as ALUNBRIG may reduce their effectiveness. Co-administration of ALUNBRIG with substrates of P-glycoprotein, breast cancer resistance protein, organic cation transporter 1, multidrug and toxin extrusion protein (MATE) 1 and 2K may increase their plasma concentrations. Patients should be closely monitored when ALUNBRIG is co-administered with substrates of these transporters with a narrow therapeutic index. **Fertility, pregnancy and lactation:** Women of reproductive potential should be advised not to become pregnant and to use effective non-hormonal contraception during treatment with ALUNBRIG and for at least 4 months following the final dose. Men should be advised not to father a child during ALUNBRIG treatment. Men with female partners of reproductive potential should be advised to use effective contraception during and for at least 3 months after the last ALUNBRIG treatment. No clinical data on the use of ALUNBRIG in pregnant women. ALUNBRIG should not be used during pregnancy unless the clinical condition of the mother requires treatment. Breast-feeding should be stopped during treatment with ALUNBRIG. No human data are available on the effect of ALUNBRIG on fertility. **Effects on ability to drive and use machines:** ALUNBRIG has minor influence on the ability to drive and use machines. However, caution should be exercised when driving or operating machines as patients may experience visual disturbance, dizziness, or fatigue while taking ALUNBRIG. **Undesirable effects:** The most common adverse reactions (≥25%) reported in patients treated with ALUNBRIG at the recommended dosing regimen were increased AST, increased CPK, hyperglycaemia, increased lipase hyperinsulinaemia, diarrhoea, increased ALT, increased amylase, anaemia, nausea, fatigue, hypophosphataemia, decreased lymphocyte count, cough, increased alkaline phosphatase, rash, increased APTT, myalgia, headache, hypertension, decreased white blood cell count, dyspnoea and vomiting. Additional very common adverse reactions (≥1/10) (all grades): Pneumonia, upper respiratory tract infection, neutrophil count decreased, hypomagnesaemia, hypercalcaemia, hyponatraemia, hypokalaemia, decreased appetite, peripheral neuropathy, dizziness, visual disturbance, abdominal pain, constipation, stomatitis, pruritus, arthralgia, blood creatinine increased, oedema, pyrexia. Common adverse reactions (≥1/100 to <1/10) (all grades): Decreased platelet count, insomnia, memory impairment, dysgeusia, bradycardia, electrocardiogram QT prolonged, tachycardia, palpitations, pneumonitis, dry mouth, dyspepsia, flatulence, blood lactate dehydrogenase increased, hyperbilirubinaemia, dry skin, photosensitivity reaction, musculoskeletal chest pain, pain in extremity, musculoskeletal stiffness, non-cardiac chest pain, chest discomfort, pain, blood cholesterol increased, weight decreased. Very common adverse reactions (≥1/10) (Grade 3-4): Lymphocyte count decreased, hypertension, lipase increased, blood CPK increased. Common adverse reactions (≥1/100 to <1/10) (Grade 3-4): Pneumonia, APTT increased, anaemia, hypophosphataemia, hyperglycaemia, hyponatraemia, hypokalaemia, decreased appetite, headache, peripheral neuropathy, visual disturbance, electrocardiogram QT prolonged, pneumonitis, dyspnoea, amylase increased, nausea, abdominal pain, diarrhoea, ALT increased, AST increased, alkaline phosphatase increased, rash, photosensitivity reaction, fatigue, weight decreased. Uncommon adverse reactions (≥ 1/1000 to <1/100) (Grade 3-4): Neutrophil count decreased, dizziness, bradycardia, vomiting, stomatitis, dyspepsia, pancreatitis, hyperbilirubinaemia, dry skin, pruritus, pain in extremity, musculoskeletal chest pain, myalgia, pyrexia, oedema, non-cardiac chest pain, weight decreased. Serious adverse reactions: The most common serious adverse reactions (≥2%) reported in patients treated with ALUNBRIG at the recommended dosing regimen other than events related to neoplasm progression were pneumonia, pneumonitis, dyspnoea and pyrexia. **Refer to the SmPC for details on full side effect profile and interactions. Legal classification:** POM. **Marketing authorisation (MA) numbers:** EU/1/18/1264/011, EU/1/18/1264/008, EU/1/18/1264/010, EU/1/18/1264/012. **Name and address of MA holder:** Takeda Pharma A/S, Delta Park 45, 2665 Vallensbaek Strand, Denmark. Additional information is available on request at: medinfoemea@takeda.com. **PI approval code:** pi-03914. **Date of Preparation:** December 2025.

Adverse Events should be reported to the Pharmacovigilance Unit at the Health Products Regulatory Authority. Reporting forms and information can be found at: www.hpra.ie. Adverse events should also be reported to Takeda at: AE.GBR-IRL@takeda.com

NOTES

NOTES



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