ZEPZELCA® (lurbinectedin) for injection 4 mg

For your adult patients with metastatic small cell lung cancer (mSCLC) with disease progression on or after platinum-based chemotherapy

A GUIDE TO ZEPZELCA

FOR ADVANCED PRACTICE PROVIDERS AND PHARMACISTS

INDICATION

ZEPZELCA® (lurbinectedin) is indicated for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

Myelosuppression

ZEPZELCA can cause myelosuppression. In clinical studies of 554 patients with advanced solid tumors receiving ZEPZELCA, Grade 3 or 4 neutropenia occurred in 41% of patients, with a median time to onset of 15 days and a median duration of 7 days. Febrile neutropenia occurred in 7% of patients.

Sepsis occurred in 2% of patients and was fatal in 1% (all cases occurred in patients with solid tumors other than SCLC). Grade 3 or 4 thrombocytopenia occurred in 10%, with a median time to onset of 10 days and a median duration of 7 days. Grade 3 or 4 anemia occurred in 17% of patients.

Please see Important Safety Information throughout and full Prescribing Information.

ZEPZELCA® (lurbinectedin) offers an established, second-line treatment option in mSCLC

>4
YEARS OF EXPERIENCE

ZEPZELCA has over 4 years of experience in the clinical practice setting[1]

#1Rx

ZEPZELCA is the #1-prescribed medication in the second-line treatment of SCLC* following first-line platinum-based therapies[2]

>25k
ADULT PATIENTS TREATED

Over 25,000 adult patients treated with ZEPZELCA to date in the United States[3]

Total number of patients treated is determined as total vials sold divided by 7.46 (average vials per patient) based on SHS claims data from July 2020–July 2024.[3]
*Source: Symphony Health Solutions (SHS) claims data: July 2020–June 2024.

IMPORTANT SAFETY INFORMATION *(CONTINUED)*

Myelosuppression *(continued)*

Administer ZEPZELCA only to patients with baseline neutrophil count of at least 1,500 cells/mm^3 and platelet count of at least 100,000/mm^3.

Monitor blood counts including neutrophil count and platelet count prior to each administration. For neutrophil count less than 500 cells/mm^3 or any value less than lower limit of normal, the use of G-CSF is recommended. Withhold, reduce the dose, or permanently discontinue ZEPZELCA based on severity.

Hepatotoxicity

ZEPZELCA can cause hepatotoxicity. In clinical studies of 554 patients with advanced solid tumors receiving ZEPZELCA, Grade 3 elevations of ALT and AST were observed in 6% and 3% of patients, respectively, and Grade 4 elevations of ALT and AST were observed in 0.4% and 0.5% of patients, respectively. The median time to onset of Grade ≥3 elevation in transaminases was 8 days (range: 3 to 49), with a median duration of 7 days.

Please see Important Safety Information throughout and full Prescribing Information.

ZEPZELCA was studied in platinum-resistant and platinum-sensitive patients

>1 in 3 patients achieved an overall response in the investigator assessment[1]

- 35% (95% CI: 26–45) by investigator assessment (N=105) (primary endpoint)
  – CR=0%; PR=35%
- 30% (95% CI: 22–40) by IRC assessment (N=105)
  – CR=0%; PR=30%

Clinically meaningful duration of response[1,a]

- 5.3 months[b] (95% CI: 4.1–6.4) by investigator assessment
- 5.1 months[b] (95% CI: 4.9–6.4) by IRC assessment

[a]Duration of response analysis is based on patients who responded to treatment.
[b]Median, in months.

Study design[1,4]

The phase 2 study was a multicenter, open-label, multi-cohort trial evaluating ZEPZELCA as a single agent in 105 adult patients with advanced or metastatic SCLC with disease progression on or after platinum-based chemotherapy. Patients received ZEPZELCA 3.2 mg/m^2 by intravenous infusion every 21 days (one cycle) for a median of 4 cycles (range: 1 to 24 cycles). The median age was 60 years (range: 40 to 83 years). Baseline ECOG Performance Status was 0–1 in 92% of patients. The major efficacy outcome measure was confirmed investigator-assessed ORR. Additional efficacy outcome measures included duration of response and an independent review committee (IRC)-assessed ORR using Response Evaluation Criteria In Solid Tumors version 1.1. The proportion of patients with disease control (a complete response, partial response, or stable disease) was an exploratory outcome measure.

CI=confidence interval; CR=complete response; ECOG=Eastern Cooperative Oncology Group; IRC=independent review committee; mSCLC=metastatic small cell lung cancer; ORR=overall response rate; PR=partial response; SCLC=small cell lung cancer.

IMPORTANT SAFETY INFORMATION *(CONTINUED)*

Hepatotoxicity *(continued)*

Monitor liver function tests prior to initiating ZEPZELCA, periodically during treatment, and as clinically indicated. Withhold, reduce the dose, or permanently discontinue ZEPZELCA based on severity.

ZEPZELCA® (lurbinectedin) for injection 4 mg

Minimal infusion visits with ZEPZELCA

1-hour dosing, every 21 days

Recommended dosing[1]

3.2 mg/m²
by IV infusion over
60 MINUTES

Repeated
EVERY 21 DAYS
until disease progression or unacceptable toxicity

Initiate treatment with ZEPZELCA only if:

Absolute neutrophil count is ***≥1,500 cells/mm³*** **AND** Platelet count is ***≥100,000/mm³***

Premedication[1]

Consider administering the following pre-infusion medications for antiemetic prophylaxis:

- **Corticosteroids (IV dexamethasone 8 mg or equivalent)**
- **Serotonin antagonists (IV ondansetron 8 mg or equivalent)**

A straightforward dose-reduction schedule to help manage adverse reactions[1]

1ST DOSE REDUCTION: 2.6 mg/m² every 21 days

2ND DOSE REDUCTION: 2 mg/m² every 21 days

Permanently discontinue ZEPZELCA in patients who[1]

Are unable to tolerate ***2 mg/m²*** every 21 days **OR** Require a dose delay ***>2 weeks***

Please see Important Safety Information throughout and full Prescribing Information.

Dosage modifications for adverse reactions[1]

Adverse reaction	Severity[a]	Dose modification
Neutropenia[b]	Grade 4 or any grade febrile neutropenia	• Withhold ZEPZELCA until Grade ≤1 • Resume ZEPZELCA at a reduced dose
Thrombocytopenia	Grade 3 with bleeding or Grade 4	• Withhold ZEPZELCA until platelet ≥100,000/mm³ • Resume ZEPZELCA at reduced dose
Hepatotoxicity	Grade 2	• Withhold ZEPZELCA until Grade ≤1 • Resume ZEPZELCA at same dose
	Grade ≥3	• Withhold ZEPZELCA until Grade ≤1 • Resume ZEPZELCA at reduced dose or permanently discontinue
Rhabdomyolysis	Grade 2	• Withhold ZEPZELCA until Grade ≤1 • Resume ZEPZELCA at same dose
	Grade ≥3	• Permanently discontinue ZEPZELCA
Other adverse reactions	Grade 2	• Withhold ZEPZELCA until Grade ≤1 • Resume ZEPZELCA at same dose
	Grade ≥3	• Withhold ZEPZELCA until Grade ≤1 • Resume ZEPZELCA at reduced dose or permanently discontinue

[a]National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 4.0.

[b]Patients with isolated Grade 4 neutropenia (neutrophil count <500 cells/mm³) may receive granulocyte colony-stimulating factor (G-CSF) prophylaxis rather than undergo lurbinectedin dose reduction.

- **For neutrophil count <500 cells/mm³ or any value less than lower limit of normal, the use of G-CSF is recommended[1]**

IV=intravenous.

IMPORTANT SAFETY INFORMATION *(CONTINUED)*

Extravasation Resulting in Tissue Necrosis

Extravasation of ZEPZELCA resulting in skin and soft tissue injury, including necrosis requiring debridement, can occur. Consider use of a central venous catheter to reduce the risk of extravasation, particularly in patients with limited venous access. Monitor patients for signs and symptoms of extravasation during the ZEPZELCA infusion.

If extravasation occurs, immediately discontinue the infusion, remove the infusion catheter, and monitor for signs and symptoms of tissue necrosis. The time to onset of necrosis after extravasation may vary.

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Preparation, administration, and storage

ZEPZELCA is a hazardous drug. Follow applicable special handling and disposal procedures[1]

PREPARATION[1]

INJECT

- Inject 8 mL of Sterile Water for Injection USP into the vial, yielding a solution containing 0.5 mg/mL of ZEPZELCA. Shake the vial until complete dissolution

INSPECT

- Visually inspect the solution for particulate matter and discoloration. The reconstituted solution is a clear, colorless, or slightly yellowish solution, essentially free of visible particles

CALCULATE

- Calculate the required volume of reconstituted solution as follows:

$$\text{Volume (mL)} = \frac{\text{Body Surface Area (m}^2\text{) x Individual Dose (mg/m}^2\text{)}}{\text{0.5 mg/mL}}$$

WITHDRAW

- Central venous line: Withdraw the appropriate amount of reconstituted solution from the vial and add to an infusion container containing at least 100 mL of diluent*
- Peripheral venous line: Withdraw the appropriate amount of reconstituted solution from the vial and add to an infusion container containing at least 250 mL of diluent*

ADMINISTRATION[1]

INSPECT

- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If particulate matter is observed, do not administer

ADMINISTER

- ZEPZELCA can be administered with or without an in-line filter. If infusion lines containing in-line filters are utilized for administration of ZEPZELCA, polyethersulfone (PES) in-line filters with pore sizes of 0.22 micron are recommended
  - Do not use in-line nylon membrane filters when the reconstituted ZEPZELCA solution is diluted using 0.9% Sodium Chloride Injection, USP. Adsorption of ZEPZELCA to the nylon membrane filters has been observed when 0.9% Sodium Chloride Injection, USP is used as the diluent
- Compatibility with other intravenous administration materials and the diluted ZEPZELCA solution has been demonstrated in the following materials:
  - Containers: Polyolefin containers (polyethylene, polypropylene, and mixtures)
  - Infusion sets: Polyvinyl Chloride (PVC) (non-DEHP-containing), polyurethane, and polyolefin infusion sets (polyethylene, polypropylene, and polybutadiene)
  - Implantable venous access systems with titanium and plastic resin ports and with polyurethane or silicone intravenous catheters

DO NOT COADMINISTER

- Do not coadminister ZEPZELCA and other intravenous drugs concurrently within the same intravenous line

STORAGE OF INFUSION SOLUTION[1]

STORE

- If not used immediately after reconstitution or dilution, the ZEPZELCA solution can be stored prior to administration for up to 24 hours following reconstitution, including infusion time, at either room temperature/ambient light or under refrigerated (2°C–8°C; 36°F–46°F) conditions

*Diluent for ZEPZELCA should be 0.9% Sodium Chloride Injection USP or 5% Dextrose Injection USP.

DEHP=Di(2-ethylhexyl) phthalate; USP=United States Pharmacopeia.

IMPORTANT SAFETY INFORMATION *(CONTINUED)*

Extravasation Resulting in Tissue Necrosis *(continued)*

Administer supportive care and consult with an appropriate medical specialist as needed for signs and symptoms of extravasation. Administer subsequent infusions at a site that was not affected by extravasation.

Rhabdomyolysis

Rhabdomyolysis has been reported in patients treated with ZEPZELCA.

Monitor creatine phosphokinase (CPK) prior to initiating ZEPZELCA and periodically during treatment as clinically indicated. Withhold or reduce the dose based on severity.

Please see Important Safety Information throughout and full Prescribing Information.

IMPORTANT SAFETY INFORMATION *(CONTINUED)*

Embryo-Fetal Toxicity

ZEPZELCA can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise female patients of reproductive potential to use effective contraception during treatment with ZEPZELCA and for 6 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ZEPZELCA and for 4 months after the last dose.

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>4 years in clinical use:

ZEPZELCA has an established safety profile

Most adverse reactions were[1,5]
GRADE 1 OR 2

- **1.9% of patients (2 of 105) permanently discontinued due to adverse reactions[1]**
  – Adverse reactions resulting in permanent discontinuation in ≥1% of patients included peripheral neuropathy and myelosuppression
- **Dose reductions due to an adverse reaction occurred in 25% of patients[1]**
  – Adverse reactions requiring dosage reductions in ≥3% of patients included neutropenia, febrile neutropenia, and fatigue
- **Dose interruptions due to an adverse reaction occurred in 30.5% of patients[1]**
  – Adverse reactions requiring dosage interruptions in ≥3% of patients included neutropenia and hypoalbuminemia

Adverse reactions (≥10%) in patients with SCLC[1]

Adverse Reaction	ZEPZELCA (N=105)	
	All Grades[a,b] (%)	Grades 3–4 (%)
General disorders		
Fatigue	77	12
Pyrexia	13	0
Chest pain	10	0
Gastrointestinal disorders		
Nausea	37	0
Constipation	31	0
Vomiting	22	0
Diarrhea	20	4
Abdominal pain[c]	11	1
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain[d]	33	4
Metabolism and nutrition disorders		
Decreased appetite	33	1
Respiratory, thoracic, and mediastinal disorders		
Dyspnea	31	6
Cough[e]	20	0
Infections and infestations		
Respiratory tract infection[f]	18	5
Pneumonia[g]	10	7
Nervous system disorders		
Peripheral neuropathy[h]	11	1
Headache	10	1

- **Alopecia occurred in 1% of patients[5]**

Select laboratory abnormalities (≥20%) worsening from baseline[1]

Laboratory abnormalities	ZEPZELCA[i] (N=105)	
	All Grades[j] (%)	Grades 3–4 (%)
Hematology		
Decreased leukocytes	79	29
Decreased lymphocytes	79	43
Decreased hemoglobin	74	10
Decreased neutrophils	71	46
Decreased platelets	37	7
Chemistry		
Increased creatinine	69	0
Increased alanine aminotransferase	66	4
Increased glucose	52	5
Decreased albumin	32	1
Decreased sodium	31	7
Increased aspartate aminotransferase	26	2
Decreased magnesium	22	0

- **In the phase 2 study, 22% of patients received granulocyte colony-stimulating factor (G-CSF) for secondary prophylaxis or therapy for neutropenia, but primary prophylaxis was not allowed[1,4]**

[a]Graded per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) 4.0.
[b]No grade 5 adverse reactions were reported.
[c]Includes abdominal pain, abdominal pain upper, and abdominal discomfort.
[d]Includes musculoskeletal pain, back pain, arthralgia, pain in extremity, musculoskeletal chest pain, neck pain, bone pain, and myalgia.
[e]Includes cough and productive cough.
[f]Includes upper respiratory tract infection, viral upper respiratory tract infection, respiratory tract infection, and bronchitis.
[g]Includes pneumonia and lung infection.
[h]Includes neuropathy peripheral, neuralgia, paresthesia, peripheral sensory neuropathy, hypoesthesia, and hyperesthesia.
[i]The denominator used to calculate the rate varied from 95 to 105 based on the number of patients with a baseline value and at least one post-treatment value.
[j]Graded per NCI CTCAE 4.0.

SCLC=small cell lung cancer.

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Monitoring guidelines for ZEPZELCA

Monitoring[1]	
Myelosuppression	• Administer ZEPZELCA only to patients with baseline neutrophil count of at least 1,500 cells/mm^3 and platelet count of at least 100,000/mm^3 • Monitor blood counts including neutrophil count and platelet count prior to each administration • For neutrophil count less than 500 cells/mm^3 or any value less than lower limit of normal, the use of G-CSF is recommended • Withhold, reduce the dose, or permanently discontinue ZEPZELCA based on severity
Hepatotoxicity	• Monitor liver function tests prior to initiating ZEPZELCA and periodically during treatment as clinically indicated • Withhold, reduce the dose, or permanently discontinue ZEPZELCA based on severity
Extravasation Resulting in Tissue Necrosis	• Consider use of a central venous catheter to reduce the risk of extravasation, particularly in patients with limited venous access • Monitor patients for signs and symptoms of extravasation during the ZEPZELCA infusion • If extravasation occurs, immediately discontinue the infusion, remove the infusion catheter, and monitor for signs and symptoms of tissue necrosis • The time to onset of necrosis after extravasation may vary • Administer supportive care and consult with an appropriate medical specialist as needed for signs and symptoms of extravasation • Administer subsequent infusions at a site that was not affected by extravasation
Rhabdomyolysis	• Monitor creatine phosphokinase (CPK) prior to initiating ZEPZELCA and periodically during treatment as clinically indicated • Withhold or reduce the dose based on severity

Patient Counseling Information[1]

KEY SIGNS AND SYMPTOMS THAT REQUIRE IMMEDIATE ATTENTION

Myelosuppression: Advise patients to immediately contact their healthcare provider for fever, other signs of infection, unusual bruising, bleeding, tiredness, or pallor

Hepatotoxicity: Advise patients to contact their healthcare provider immediately for signs and symptoms suggestive of hepatotoxicity

Extravasation Resulting in Tissue Necrosis: Advise patients to contact their healthcare provider immediately for signs and symptoms of extravasation. The time to onset of necrosis after extravasation may vary

Rhabdomyolysis: Advise patients to contact their healthcare provider immediately for signs and symptoms of rhabdomyolysis

PREGNANCY AND REPRODUCTIVE HEALTH CONSIDERATIONS

Embryo-Fetal Toxicity:

- Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females to inform their healthcare provider of a known or suspected pregnancy
- Advise females of reproductive potential to use effective contraception during treatment with ZEPZELCA and for 6 months after the last dose
- Advise males with female partners of reproductive potential to use effective contraception during treatment with ZEPZELCA and for 4 months after the last dose

Lactation: Advise women not to breastfeed during treatment with ZEPZELCA and for at least 2 weeks after the last dose

DISCLOSING CONCOMITANT MEDICATIONS

Drug Interactions: Advise patients to inform their healthcare providers of all concomitant medications and herbal and dietary supplements. Advise patients to avoid products that contain grapefruit juice and Seville oranges during treatment with ZEPZELCA

G-CSF=granulocyte colony-stimulating factor.

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Access and support through JazzCares

JazzCares is committed to helping your patients get access to their ZEPZELCA® (lurbinectedin) medication and providing personalized support throughout their treatment

JazzCares®
Making a difference in Patients' lives, one Patient at a time

JAZZCARES SUPPORTS PATIENTS AND PRACTICES

- Assists you with benefits investigations, prior authorizations and appeals, and referrals to other financial assistance options for eligible patients

FREE DRUG PROGRAM FOR ELIGIBLE PATIENTS

- Uninsured or underinsured patients who are eligible may receive ZEPZELCA at no cost

REDUCTION OF OUT-OF-POCKET COSTS FOR ELIGIBLE PATIENTS

- Savings Card—Eligible, commercially insured patients can pay as little as $10

Learn more about JazzCares support offerings by calling 1-833-533-JAZZ (5299) Monday–Friday, 8 AM to 8 PM ET, or visit JazzCares.com

Insurance coverage and plans may vary. The JazzCares program at Jazz Pharmaceuticals provides general information only and is not a guarantee of any coverage or reimbursement outcome. All treatment decisions rest solely with the treating physician or qualified healthcare professional. Jazz Pharmaceuticals reserves the right to terminate or modify this program at any time with or without notice. Other terms and conditions apply.

Reimbursement for ZEPZELCA® (lurbinectedin)

J-CODE ISSUED FOR ZEPZELCA	DESCRIPTION[a]
J9223	***Infusion: 3.2 mg/m²***

HCPCS CODE DOSAGE	EXAMPLE
0.1 mg = 1 unit	***4 mg vial = 40 units***

[a]The HCPCS Level II code J9233 became effective for Medicare Part B patients starting on January 1, 2021. Please check with commercial and Medicaid resources for the effective date.

Please see Important Safety Information throughout and full Prescribing Information.

Ordering ZEPZELCA

Specialty Distributors

ZEPZELCA is available for purchase from the authorized specialty distributors listed below. Verify that your facility has an account with their specialty distributor before ordering. If not, please contact the specialty distributor. You may also contact the distributor with questions regarding product returns.

Cencora (formerly AmerisourceBergen)

AmerisourceBergen Specialty Distribution (ASD)

- Orders can be placed Monday–Thursday, 7 AM–6:30 PM CT; Friday, 7 AM–6 PM CT
- For emergency orders after hours of service, call 1-800-746-6273

www.asdhealthcare.com
1-800-746-6273
1-800-547-9413
asd.customerservice@asdhealthcare.com

Oncology Supply

- Orders can be placed Monday–Friday, 6 AM–10 PM CT; Saturday–Sunday, 7:30 AM–7 PM CT
- If orders are placed after hours via email, they will be managed on the morning of the next business day

www.oncologysupply.com
1-800-633-7555
1-800-248-8205
custserv@oncologysupply.com

McKesson

McKesson Plasma and Biologics (MPB)

- Orders can be placed Monday–Friday, 9 AM–7:30 PM ET
- Email for all other information requests: MPB@mckesson.com
- For emergency orders after hours of service, call 1-877-625-2566

connect.mckesson.com
1-877-625-2566
1-888-752-7626
MPBOrders@mckesson.com

McKesson Specialty Health (MSH)

- Orders can be placed Monday–Friday, 8 AM–8 PM ET
- If orders are placed after hours via email, they will be managed on the morning of the next business day

mscs.mckesson.com
1-800-482-6700
1-800-289-9285
MSH-CustomerCare@mckesson.com

Cardinal Health

Cardinal Specialty Pharmaceutical Distribution (SPD)

- Orders can be placed Monday–Friday, 8 AM–7 PM CT
- For emergency orders after hours of service, call 1-877-453-3972

Order Express (Hospitals): orderexpress.cardinalhealth.com

Specialty Online (Clinics): specialtyonline.cardinalhealth.com

1-877-453-3972
1-877-274-9897
SPDOncologyTeam@cardinalhealth.com

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2025 NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®):

Lurbinectedin (ZEPZELCA®) is preferred when CTFI ≤6 months and recommended when CTFI >6 months[6]

National Comprehensive Cancer Network® (NCCN®) guidance for lurbinectedin (ZEPZELCA) as a subsequent SCLC therapy option (ECOG PS 0–2)[6*†]

NCCN CATEGORY 2A RECOMMENDATION

CTFI ≤6 months	CTFI >6 months
PREFERRED REGIMEN[‡]	***RECOMMENDED REGIMEN***[§]

Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus (≥85% support of the Panel) that the intervention is appropriate.

*Subsequent systemic therapy refers to second-line and beyond therapy.[6]
†See the NCCN Guidelines® for SCLC for detailed recommendations, including other treatment options.
‡Preferred interventions are based on superior efficacy, safety, and evidence, and, when appropriate, affordability.[6]
§Other recommended interventions may be somewhat less efficacious, more toxic, or based on less mature data, or are significantly less affordable for similar outcomes.[6]

CTFI=chemotherapy-free interval; ECOG PS=Eastern Cooperative Oncology Group Performance Status; NCCN=National Comprehensive Cancer Network® (NCCN®); SCLC=small cell lung cancer.

IMPORTANT SAFETY INFORMATION *(CONTINUED)*

Lactation

There are no data on the presence of ZEPZELCA in human milk, however, because of the potential for serious adverse reactions from ZEPZELCA in breastfed children, advise women not to breastfeed during treatment with ZEPZELCA and for 2 weeks after the last dose.

Please see Important Safety Information throughout and full Prescribing Information.

References: 1. ZEPZELCA (lurbinectedin) Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc. **2.** Data on file-REF-17819. Jazz Pharmaceuticals, Inc. **3.** Data on file-REF-18136. Jazz Pharmaceuticals, Inc. **4.** Trigo J, Subbiah V, Besse B, et al. Lurbinectedin as second-line treatment for patients with small-cell lung cancer: a single-arm, open-label, phase 2 basket trial. *Lancet Oncol*. 2020;21(5):645–654. **5.** Data on file-LUR-2020-003. Jazz Pharmaceuticals, Inc. **6.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Small Cell Lung Cancer. V.2.2025. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed September 5, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org.

IMPORTANT SAFETY INFORMATION *(CONTINUED)*

MOST COMMON ADVERSE REACTIONS

The most common adverse reactions, including laboratory abnormalities, (≥20%) are leukopenia (79%), lymphopenia (79%), fatigue (77%), anemia (74%), neutropenia (71%), increased creatinine (69%), increased alanine aminotransferase (66%), increased glucose (52%), thrombocytopenia (37%), nausea (37%), decreased appetite (33%), musculoskeletal pain (33%), decreased albumin (32%), constipation (31%), dyspnea (31%), decreased sodium (31%), increased aspartate aminotransferase (26%), vomiting (22%), decreased magnesium (22%), cough (20%), and diarrhea (20%).

DRUG INTERACTIONS

Effect of CYP3A Inhibitors and Inducers

Avoid coadministration with a strong or a moderate CYP3A inhibitor (including grapefruit and Seville oranges) as this increases lurbinectedin systemic exposure which may increase the incidence and severity of adverse reactions to ZEPZELCA. If coadministration cannot be avoided, reduce the ZEPZELCA dose as appropriate.

Avoid coadministration with a strong CYP3A inducer as it may decrease systemic exposure to lurbinectedin, which may decrease the efficacy of ZEPZELCA.

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PURSUE WHAT MATTERS
with ZEPZELCA® (lurbinectedin)

In a phase 2 study of 105 adults with SCLC who progressed on or after platinum-based chemotherapy,

ZEPZELCA was studied across platinum-resistant and platinum-sensitive subgroups[1]

PRIMARY ENDPOINT

- Overall response rate as assessed by study investigators[4]

SECONDARY ENDPOINT

- Duration of response[4]

1-HOUR ADMINISTRATION, every 21 days[1]

3.2 mg/m^2 by intravenous infusion over 60 minutes, repeated every 21 days until disease progression or unacceptable toxicity.

Initiate treatment with ZEPZELCA only if absolute neutrophil count is ≥1,500 cells/mm^3 and platelet count is ≥100,000/mm^3.

ZEPZELCA has an established safety profile derived from clinical data[1]

EXPLORE ZEPZELCA

SCLC=small cell lung cancer.

IMPORTANT SAFETY INFORMATION *(CONTINUED)*

GERIATRIC USE

Of the 105 patients with SCLC administered ZEPZELCA in clinical studies, 37 (35%) patients were 65 years of age and older, while 9 (9%) patients were 75 years of age and older. No overall difference in effectiveness was observed between patients aged 65 and older and younger patients.

There was a higher incidence of serious adverse reactions in patients ≥65 years of age than in patients <65 years of age (49% vs 26%, respectively). The serious adverse reactions most frequently reported in patients ≥65 years of age were related to myelosuppression and consisted of febrile neutropenia (11%), neutropenia (11%), thrombocytopenia (8%), and anemia (8%).

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Jazz Pharmaceuticals | PharmaMar