

<p style="text-align: center;">PATIENT INFORMATION ZEPZELCA® (zep zel' kah) (lurbinectedin) for injection</p>
<p>What is ZEPZELCA?</p> <ul style="list-style-type: none"> • ZEPZELCA is used to treat adults with a kind of lung cancer called small cell lung cancer (SCLC). ZEPZELCA may be used when your lung cancer: <ul style="list-style-type: none"> ○ has spread to other parts of the body (metastatic), and ○ you have received treatment with chemotherapy that contains platinum, and it did not work or is no longer working. <p>It is not known if ZEPZELCA is safe and effective in children.</p>
<p>Before receiving ZEPZELCA, tell your healthcare provider about all of your medical conditions, including if you:</p> <ul style="list-style-type: none"> • have liver or kidney problems. • are pregnant or plan to become pregnant. ZEPZELCA can harm your unborn baby. <p>Females who are able to become pregnant:</p> <ul style="list-style-type: none"> ○ Your healthcare provider should do a pregnancy test before you start treatment with ZEPZELCA. ○ You should use effective birth control (contraception) during treatment with and for 6 months after your last dose of ZEPZELCA. ○ Tell your healthcare provider right away if you become pregnant or think that you are pregnant during treatment with ZEPZELCA. <p>Males with female partners who are able to become pregnant should use effective birth control during treatment with and for 4 months after your last dose of ZEPZELCA.</p> <ul style="list-style-type: none"> • are breastfeeding or plan to breastfeed. It is not known if ZEPZELCA passes into your breastmilk. Do not breastfeed during treatment with ZEPZELCA and for 2 weeks after your last dose of ZEPZELCA. Talk to your healthcare provider about the best way to feed your baby during treatment with ZEPZELCA. <p>Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Certain other medicines may affect how ZEPZELCA works. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.</p>
<p>How will I receive ZEPZELCA?</p> <ul style="list-style-type: none"> • ZEPZELCA is given by an intravenous (IV) infusion into a vein over 60 minutes. • ZEPZELCA is usually given every 21 days. • Before each treatment with ZEPZELCA, you may receive medicines to help prevent nausea and vomiting or make it less severe. • Your healthcare provider will decide how long you will continue treatment with ZEPZELCA. • Your healthcare provider may do certain tests during your treatment with ZEPZELCA to check you for side effects, and to see how well you respond to the treatment.
<p>What should I avoid while using ZEPZELCA?</p> <ul style="list-style-type: none"> • Avoid eating or drinking grapefruit, Seville oranges, or products that contain grapefruit juice and Seville oranges during treatment with ZEPZELCA.

What are the possible side effects of ZEPZELCA?**ZEPZELCA can cause serious side effects, including:**

- **Low blood cell counts.** Low blood counts including low neutrophil counts (neutropenia) and low platelet counts (thrombocytopenia) are common with ZEPZELCA, and can also be severe. Some people with low white blood cell counts may get fever, or an infection throughout the body (sepsis), that can cause death. Your healthcare provider should do blood tests before you receive each treatment with ZEPZELCA to check your blood cell counts.

Tell your healthcare provider right away if you develop:

- fever or any other signs of infection
- tiredness
- unusual bruising or bleeding
- pale colored skin

- **Liver problems.** Increased liver function tests are common with ZEPZELCA and can also be severe. Your healthcare provider should do blood tests to check your liver function before you start and during treatment with ZEPZELCA.

Tell your healthcare provider right away if you develop symptoms of liver problems including:

- loss of appetite
- nausea or vomiting
- pain on the right side of your stomach-area (abdomen)

- **Leakage of ZEPZELCA out of your vein during the infusion.** If ZEPZELCA leaks into the tissues around your infusion site, it can cause damage and death of tissue cells around the infusion site. You may need to have surgery to remove any dead tissue. Tell your healthcare provider right away if you see any ZEPZELCA leaking out of your vein or around the catheter during your infusion, or if you notice any redness, swelling, itching or discomfort at the infusion site at any time.
- **Severe muscle problems (rhabdomyolysis).** Tell your healthcare provider if you have severe muscle pain or weakness.

Your healthcare provider may temporarily stop treatment, lower your dose, or permanently stop ZEPZELCA if you develop serious side effects during treatment with ZEPZELCA.

The most common side effects of ZEPZELCA include:

- tiredness
- constipation
- low white and red blood cell counts
- trouble breathing
- increased kidney function blood test (creatinine)
- low levels of sodium and magnesium in the blood
- increased liver function blood tests
- vomiting
- increased blood sugar (glucose)
- cough
- nausea
- diarrhea
- decreased appetite
- muscle and joint (musculoskeletal) pain
- low level of albumin in the blood

These are not all of the possible side effects of ZEPZELCA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of ZEPZELCA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about ZEPZELCA that is written for health professionals.

What are the ingredients in ZEPZELCA?**Active ingredient:** lurbinectedin**Inactive ingredients:** sucrose, lactic acid and sodium hydroxide.

Distributed by: Jazz Pharmaceuticals, Inc.
Palo Alto, CA 94306

Under license from Pharma Mar, S.A.

ZEPZELCA is a registered trademark of Pharma Mar, S.A.

For more information, go to www.ZEPZELCA.com or call 1-800-520-5568.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Revised: 7/2025