PATIENT INFORMATION ZEPZELCA[®] (zep zel' kah) (lurbinectedin) for injection

What is ZEPZELCA?

- 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:
 - \circ 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.

It is not known if ZEPZELCA is safe and effective in children.

Before receiving ZEPZELCA, tell your healthcare provider about all of your medical conditions, including if you:

- have liver or kidney problems.
- are pregnant or plan to become pregnant. ZEPZELCA can harm your unborn baby. **Females who are able to become pregnant**:
 - 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.

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.

 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.

Tell your healthcare provider about all the medicines you take, including prescription and overthe-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.

How will I receive ZEPZELCA?

- 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.

What should I avoid while using ZEPZELCA?

• 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

,	cause death. Your healthcare provider should do blood tests before you receiv
	ith ZEPZELCA to check your blood cell counts.
-	care provider right away if you develop:
 fever or any or 	other signs of infection o tiredness
 unusual bruis 	ing or bleeding or pale colored skin
severe. Your hea	Increased liver function tests are common with ZEPZELCA and can also be Ithcare provider should do blood tests to check your liver function before you
•	reatment with ZEPZELCA.
-	care provider right away if you develop symptoms of liver problems
including:	- nouses or
 loss of appetite 	 nausea or o pain on the right side of your stomach-area (abdomen)
tissues around yo infusion site. You provider right awa	ZELCA out of your vein during the infusion. If ZEPZELCA leaks into the our infusion site, it can cause damage and death of tissue cells around the may need to have surgery to remove any dead tissue. Tell your healthcare ay if you see any ZEPZELCA leaking out of your vein or around the catheter on, or if you notice any redness, swelling, itching or discomfort at the infusion
•	broblems (rhabdomyolysis). Tell your healthcare provider if you have severe eakness.
•	ider may temporarily stop treatment, lower your dose, or permanently stop velop serious side effects during treatment with ZEPZELCA.
The most common s	side effects of ZEPZELCA include:
 tiredness 	constipation
 low white and re 	ed blood cell counts
 increased kidner 	y function blood test (creatinine) • low levels of sodium and magnesium
	unction blood tests in the blood
 increased blood 	sugar (glucose) • vomiting
 nausea cough 	
 decreased appe 	6
	t (musculoskeletal) pain
 low level of albu 	· · · ·
	ne possible side effects of ZEPZELCA. Call your doctor for medical advice about
	report side effects to FDA at 1-800-FDA-1088.
	about the safe and effective use of ZEPZELCA.
	mes prescribed for purposes other than those listed in a Patient Information
	ke more information, talk with your healthcare provider. You can ask your
-	care provider for information about ZEPZELCA that is written for health
professionals.	
•	ients in ZEPZELCA?
Active ingredient: lu	
•	: sucrose, lactic acid and sodium hydroxide.
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ZEPZELCA is a registered trad For more information, go to we	lemark of Pharma Mar, S.A. <u>vw.ZEPZELCA.com</u> or call 1-800-520-5568.
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