

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **ZEPZELCA**[®]

Lurbinectedin for injection

Read this carefully before you start taking **ZEPZELCA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ZEPZELCA**.

Serious Warnings and Precautions

- ZEPZELCA will be prescribed to you by doctors who are experienced in the use of drugs to treat cancer.
- ZEPZELCA can cause serious side effects including Myelosuppression (a large decrease in the production of blood cells and platelets by the bone marrow). Symptoms include: bleeding, bruising, chills, fatigue, fever, infections, weakness, shortness of breath, or other signs of infection. Tell your healthcare professional right away if you develop new or worsening symptoms.
- ZEPZELCA may harm your unborn baby if you take it while you are pregnant.
- ZEPZELCA can leak out of your vein into the surrounding tissue (extravasation). This may lead to tissue damage after ZEPZELCA is given through a vein in your arm (intravenous administration).
- Your healthcare professional may administer ZEPZELCA through a central venous catheter (tube that is placed into the vein above the heart) to reduce the risk of developing extravasation.

What is ZEPZELCA used for?

For the following indication(s) ZEPZELCA has been approved with conditions (NOC/c). This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the drug works the way it should. For more information, talk to your healthcare professional.

- ZEPZELCA is used to treat a type of cancer called Stage III or metastatic small cell lung cancer (SCLC). It is used in adults who have received treatment with chemotherapy that contains platinum and it did not work or is no longer working.

What is a Notice of Compliance with Conditions (NOC/c)?

A Notice of Compliance with Conditions (NOC/c) is a type of approval to sell a drug in Canada.

Health Canada only gives an NOC/c to a drug that treats, prevents, or helps identify a serious or life-threatening illness. The drug must show promising proof that it works well, is of high quality, and is reasonably safe. Also, the drug must either respond to a serious medical need in Canada, or be much safer than existing treatments.

Drug makers must agree in writing to clearly state on the label that the drug was given an NOC/c, to complete more testing to make sure the drug works the way it should, to actively monitor the drug's performance after it has been sold, and to report their findings to Health Canada.

How does ZEPZELCA work?

ZEPZELCA works by preventing the cancer cells from growing and spreading to other parts in the body. ZEPZELCA also reduces the ability of other cells to support the growth of the cancer cells. This helps stop the growth of the cancer cells.

What are the ingredients in ZEPZELCA?

Medicinal ingredient: lurbinectedin

Non-medicinal ingredients: lactic acid, sodium hydroxide, sucrose

ZEPZELCA comes in the following dosage forms:

Lyophilized powder, 4 mg / vial for intravenous infusion

Do not use ZEPZELCA if:

- You are allergic to lurbinectedin or any of the other ingredients of ZEPZELCA or the container.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ZEPZELCA. Talk about any health conditions or problems you may have, including if you:

- Have liver problems
- Have kidney problems
- Have any neurological (nervous system) conditions

Other warnings you should know about:

Pregnancy:

- Tell your healthcare professional if you are pregnant or plan to become pregnant.
- ZEPZELCA can harm your unborn baby.
- If you are a woman who could become pregnant:
 - Your healthcare professional 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 final dose of ZEPZELCA.
 - Tell your healthcare professional 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:

- Use effective birth control during treatment with and for 4 months after your final dose of ZEPZELCA.
- If your partner becomes pregnant while you are taking ZEPZELCA, tell your healthcare professional right away.

Breastfeeding:

- Tell your healthcare professional if you 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 final dose of ZEPZELCA. Talk to your healthcare provider about

the best way to feed your baby during treatment with ZEPZELCA.

Children:

- ZEPZELCA should not be used in children below 18 years of age.

Rhabdomyolysis (breakdown of damaged muscle):

- ZEPZELCA may cause rhabdomyolysis which is the breakdown of damaged muscle.
- Your healthcare professional will do tests before and during treatment to check for rhabdomyolysis.
- If you get rhabdomyolysis, your healthcare professional will decide which treatments are best for you.

Driving and using machines:

- ZEPZELCA can cause fatigue, weakness, and make you feel unwell. Give yourself time after receiving treatment with ZEPZELCA to see how you feel before driving a vehicle or using machinery.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ZEPZELCA:

- Avoid eating or drinking products or juices containing grapefruit or Seville oranges.
- Avoid taking St. John's Wort during treatment with ZEPZELCA.
- Statins, a class of medicines used to lower cholesterol.

How to take ZEPZELCA:

- ZEPZELCA will be prepared in an infusion container by a pharmacist and then delivered to the healthcare professional who will administer the medication to you at the hospital.
- 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 professional will decide how long you will continue treatment with ZEPZELCA.
- Your healthcare professional 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.

Usual dose:

The recommended dose of ZEPZELCA is 3.2 mg/m² every 21 days. Your doctor will decide how much ZEPZELCA you will receive, and how many treatments you will need.

Overdose:

If you think you, or a person you are caring for, have taken too much ZEPZELCA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss any appointments, call your healthcare professional as soon as possible to reschedule your appointment. It is very important that you do not miss a dose of this medicine.

What are possible side effects from using ZEPZELCA?

These are not all the possible side effects you may have when taking ZEPZELCA. If you experience any side effects not listed here, tell your healthcare professional.

- decreased appetite
- nausea
- vomiting
- diarrhea
- tiredness
- fever
- cough
- dry mouth, altered or impaired sense of taste
- constipation
- weight loss or weight gain
- pain in the abdomen
- pain in chest
- pain in the muscles or bones
- painful swelling or sores inside the mouth
- indigestion
- darkening of the skin
- joint pain
- involuntary contractions of a muscle
- general weakness, fatigue
- dehydration
- headache
- dizziness
- shortness of breath
- skin reaction such as rash, itchiness and dry skin
- skin ulcers
- swelling in the hands or feet
- generally feeling unwell
- sensitivity to light
- difficulty swallowing
- difficulty speaking
- hiccups

ZEPZELCA can cause abnormal blood test results. Your healthcare professional will perform blood tests before and during your treatment. Your doctor will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Low blood counts including neutropenia (low neutrophils), leukopenia (decrease white blood cells), and thrombocytopenia (low platelet counts): fever or any other signs of infection, shortness of breath, tiredness, weakness, unusual bruising or bleeding, pale colored skin		√	
Anemia (decreased number of red blood cells): fatigue, loss of energy, irregular heartbeats, pale complexion, shortness of breath, weakness		√	
Gastrointestinal problems: loss of appetite, nausea or vomiting, pain on the right side of your stomach-area (abdomen)		√	
Kidney problems: nausea, vomiting, fever, swelling of extremities, fatigue, thirst, dry skin, irritability, dark urine, increased or decreased urine output, loss of appetite, abnormal blood test results		√	
Liver problems: dark urine, fatigue, loss of appetite, nausea or vomiting, sleepiness, bleeding or bruising, yellowing of the skin or eyes, pain on the upper right side of the stomach area		√	
Pneumonia (infection in the lungs): chest pain when you breathe or cough, confusion, cough which may produce phlegm, fatigue, fever, sweating and shaking, chills, nausea, vomiting or diarrhea, shortness of breath		√	
Neuropathy peripheral: weakness, numbness, and pain caused by nerve damage in the arms and legs		√	
COMMON			
Hypotension (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up)		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
Thrombophlebitis: swelling and redness along a vein which is extremely tender or painful when touched RARE	√		
Extravasation (leakage of ZEPZELCA from your vein to the tissue around it): blisters or sores, pain, tenderness, itchiness or burning at the site UNKNOWN			√
Rhabdomyolysis (breakdown of damaged muscle): muscle pain, weakness or spasms, red-brown urine			√
Tumour lysis syndrome (the sudden, rapid death of cancer cells due to the treatment): nausea, shortness of breath, irregular heartbeat, heart rhythm disturbances, lack of urination, clouding of urine, muscle spasms or twitching, tiredness and/or joint pain, severe muscle weakness, and seizures. Metabolic disorders (kidney failure, abnormal heartbeat) and abnormal blood tests due to rapid breakdown of cancer cells.			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Your healthcare professional will store, prepare, and dispose ZEPZELCA for you.

Store unopened vial in refrigerator at 2°C to 8°C.

If not used immediately after reconstitution or dilution, the diluted 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 to 8°C) conditions.

ZEPZELCA is a cytotoxic drug. Follow applicable disposal procedures. Follow applicable special handling procedures.

Keep out of reach and sight of children.

If you want more information about ZEPZELCA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.jazzpharma.com, or by calling 1-800-520-5568.

This leaflet was prepared by Jazz Pharmaceuticals Ireland Limited.

Imported / distributed by: Jazz Pharmaceuticals Canada Inc.
4080 Confederation Parkway, Suite 602, Mississauga, ON L5B 0G1

ZEPZELCA® is a registered trademark of Pharma Mar, S.A., and is used under license.

Last Revised: MAR 05, 2024