

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using ZEPZELCA?

ZEPZELCA contains the active ingredient lurbinectedin. ZEPZELCA has **provisional approval** in Australia for the treatment of patients with small cell lung cancer, when the cancer has spread to other parts of the body (is metastatic), and has previously been treated with chemotherapy that contained platinum, which either did not work or is no longer working.

For more information, see Section [1. Why am I using ZEPZELCA?](#) in the full CMI.

2. What should I know before I use ZEPZELCA?

Do not use if you have had a severe allergic reaction to lurbinectedin or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ZEPZELCA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ZEPZELCA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is ZEPZELCA given?

- The usual dose is 3.2 mg/m² of body surface area every 3 weeks
- ZEPZELCA will be given to you as an infusion (a drip) into a vein (intravenously) over a period of 60 minutes

More instructions can be found in Section [4. How is ZEPZELCA given?](#) in the full CMI.

5. What should I know while using ZEPZELCA?

Things you must do	<ul style="list-style-type: none">• If you are about to be started on any new medicine, remind your doctor that you are being given ZEPZELCA• Remind any doctor, dentist or pharmacist you visit that you are using ZEPZELCA• If you become pregnant while being given this medicine, tell your doctor immediately
Things you must not do	<ul style="list-style-type: none">• During your treatment with ZEPZELCA you may feel tired and experience loss of strength. Do not drive or use any tools or machines if you are experiencing any of these side effects

For more information, see Section [5. What should I know while using ZEPZELCA?](#) in the full CMI.

6. Are there any side effects?

Common side effects include: anemia, nausea, tiredness and decreased appetite.

Serious side effects that may require urgent medical attention or hospitalisation include: decrease in blood cell counts, serious infections and liver problems.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



This medicine is subject to additional monitoring due to provisional approval. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

ZEPZELCA[®]

Active ingredient(s): *lurbinectedin*

This medicine has **provisional registration** in Australia for the treatment of patients with metastatic small cell lung cancer (SCLC) that has progressed on or after prior platinum-containing therapy. The decision to provisionally register this medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to substantiate the benefit of the medicine for this use.

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZEPZELCA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ZEPZELCA.**

Where to find information in this leaflet:

- [1. Why am I using ZEPZELCA?](#)
- [2. What should I know before I use ZEPZELCA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is ZEPZELCA given?](#)
- [5. What should I know while using ZEPZELCA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ZEPZELCA?

ZEPZELCA contains the active ingredient lurbinectedin. ZEPZELCA is an anti-cancer medicine that works by preventing the tumour cells from multiplying.

ZEPZELCA has provisional approval for the treatment of patients with small cell lung cancer, when the cancer has spread to other parts of the body (is metastatic), and has previously been treated with chemotherapy that contained platinum, which either did not work or is no longer working.

The decision to approve this medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to fully confirm the benefit and safety of the medicine for this use.

It is not known if ZEPZELCA is safe and effective in patients under 18 years old.

2. What should I know before I use ZEPZELCA?

Do not use ZEPZELCA if:

- you are allergic to lurbinectedin, or any of the other ingredients (check the list of ingredients at the end of this leaflet to make sure you can use this medicine).

Before receiving ZEPZELCA, tell your doctor about any medical conditions you have, including if you:

- have problems or abnormal function of your liver or kidney.
- take any other medicines, including over-the-counter medicines, alternative medicines and supplements.
- are pregnant, plan to become pregnant, or are planning to have children in future.
- are breast-feeding.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Female patients who could potentially become pregnant:

- Your doctor may want to do a pregnancy test before you commence treatment with ZEPZELCA.
- You should use highly effective contraception during treatment with ZEPZELCA, and for 7 months after your final dose.
- Tell your doctor immediately if you become pregnant or think you could be pregnant during treatment with ZEPZELCA.
- It is not known if ZEPZELCA passes into breastmilk. You should not breastfeed during treatment with ZEPZELCA.

Male patients with female partners who could potentially become pregnant:

- You should use highly effective contraception during treatment with ZEPZELCA, and for 4 months after your final dose.

Fertility

If you may wish to have children in future, seek medical advice on fertility preservation treatment prior to therapy with ZEPZELCA, because ZEPZELCA may cause irreversible infertility.

Genetic counselling is also recommended for patients wishing to have children after ZEPZELCA therapy.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ZEPZELCA and affect how it works, therefore you should avoid the use of ZEPZELCA together with the medicines listed below.

Medicines that may increase the effect of ZEPZELCA include medicines that contain:

- Ketoconazole, itraconazole, posaconazole, voriconazole or fluconazole (for fungal infections),
- ciprofloxacin and erythromycin (for bacterial infections),
- aprepitant (to prevent nausea and vomiting),
- fluvoxamine (for depression and obsessive compulsive disorder [OCD])
- imatinib (for certain types of leukaemia's) or
- verapamil and diltiazem (for high blood pressure and heart conditions).

Avoid grapefruit products such as grapefruit and grapefruit juice. These products may contain components that increase the effect of ZEPZELCA.

Medicines that may reduce the effect of ZEPZELCA include medicines that contain:

- rifampicin (for bacterial infections),
- phenobarbital, carbamazepine and primidone (for epilepsy)
- bosentan (for high blood pressure in the lungs) or
- St. John's Wort (*Hypericum perforatum*, an herbal medicine for depression).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and/or whether they could affect (or be affected by) ZEPZELCA.

4. How is ZEPZELCA given?

ZEPZELCA is given to you in the hospital or clinic under the supervision of a physician experienced in the use of chemotherapy. Its use should be confined to qualified oncologists or other health professionals specialised in the administration of anti-cancer medicines.

How much is given

- The usual dose is 3.2 mg/m² of body surface area, once every 3 weeks.

- During the treatment period, your doctor will carefully monitor you and decide the most appropriate dosage of ZEPZELCA to give to you.

How it is given

- ZEPZELCA is given as an intravenous (IV) infusion (through a drip into a vein) over a period of 60 minutes.
- ZEPZELCA can be given through a peripheral or central venous line.
- You may be given additional medicines before each treatment (and as needed during the treatment) to help prevent nausea and vomiting, or make it less severe.

How long it will be given for

- The infusion is usually given once every 3 weeks, but your doctor may recommend dose delays if needed to manage side effects.
- The length of your whole treatment period will be determined by your doctor, depending on your progress and how well you feel.

If too much is given (overdose)

As this medicine is being given by your doctor or nurse, it is unlikely that you will be given too much.

In the unlikely event of an overdose, your doctor will monitor you for side effects and treat any symptoms as required.

If you have any further questions on the use of this medicine, ask your doctor.

5. What should I know while using ZEPZELCA?

During treatment with ZEPZELCA, you must inform your doctor or nurse if you feel any of the symptoms mentioned under *Section 6. Are there any side effects?*. Your doctor might reduce or delay the ZEPZELCA dose, or recommend that you stop treatment, depending on the severity.

Things you must do

- If you are about to be started on any new medicine, remind your doctor that you are being given ZEPZELCA.
- Remind any doctor, dentist or pharmacist you visit that you are using ZEPZELCA.
- You should use highly effective birth control (contraception) during treatment with and for 7 months after your final dose of ZEPZELCA. Males with female partners who are able to become pregnant should use highly effective birth control during treatment with and for 4 months after your final dose of ZEPZELCA.

- Tell your doctor or nurse straight away if you experience an allergic reaction or feel unwell during infusion.

Typical symptoms associated with allergic reactions are redness of the face or chest, itching, coughing, shortness of breath, chest discomfort, etc. Other symptoms may occur as well.

These side effects mostly occur during or after the infusion of the first dose. You will be monitored for signs of these effects during and after the infusion.

Call your doctor straight away if you become pregnant while being given this medicine.

Things you must not do

During your treatment with ZEPZELCA you may feel tired and experience loss of strength. Do not drive or use any tools or machines if you are experiencing any of these side effects.

Storage

ZEPZELCA will be stored in the pharmacy or on the ward. The medicine is kept in its original packaging in the refrigerator where the temperature stays between 2°C and 8°C.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Your doctor will perform certain checks periodically to test for side effects that may affect the blood, liver, kidneys, heart and muscle.

Less serious side effects

Less serious side effects	What to do
<p>General or affecting different parts of the body:</p> <ul style="list-style-type: none"> • Tiredness • Muscle and joint pains <p>Stomach and digestive system related:</p> <ul style="list-style-type: none"> • Nausea and vomiting • Diarrhoea • Constipation • Decreased appetite 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>General or affecting different parts of the body:</p> <ul style="list-style-type: none"> • Low neutrophil counts (neutropenia), which can lead to an infection throughout the body (sepsis), with symptoms such as fever, chills, sweating, shortness of breath or feeling unwell. • Serious infections may occur even without decreased white blood cell counts. • Low platelet counts (thrombocytopenia), which may result in unusual bleeding or bruising. • Low red blood cell counts (anaemia), which may result in severe tiredness, pale appearance or shortness of breath. • Liver problems, with symptoms such as loss of appetite, nausea or vomiting, or pain on the upper right side of your abdomen (stomach area). • 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. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ZEPZELCA contains

Active ingredient (main ingredient)	Lurbinectedin
Other ingredients (inactive ingredients)	(S)-lactic acid Sucrose Sodium hydroxide Water for Injection

Do not take this medicine if you are allergic to any of these ingredients.

What ZEPZELCA looks like

ZEPZELCA is a powder for solution for intravenous infusion. The powder has a white to off-white colour. (Aust R 335536).

Who distributes ZEPZELCA

Specialised Therapeutics
Pharma Pty Ltd
Level 2, 17 Cotham Road,
Kew, Victoria, 3101

Ph: 1300 798 820
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www.stbiopharma.com

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