

ZEPZELCA

lurbinectedin

Consumer Medicine Information

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.

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 effective contraception during treatment with ZEPZELCA, and for 6 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 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.