Consumer Medicine Information

This medicine has provisional approval in Australia to treat adult patients with nonsmall cell lung cancer (NSCLC) that has spread to other parts of the body or is advanced, and whose tumours have mesenchymal-epithelial transition (MET) exon 14 skipping alterations. The decision to approve TEPMETKO has been made based on 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.

This leaflet provides important information about using TEPMETKO. 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 TEPMETKO.

Where to find information in this leaflet:

- 1. Why am I using TEPMETKO?
- 2. What should I know before I use TEPMETKO?
- 3. What if I am taking other medicines?
- 4. How do I use TEPMETKO?
- 5. What should I know while using TEPMETKO?
- 6. Are there any side effects?
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1. Why am I using TEPMETKO?

TEPMETKO contains the active ingredient tepotinib (as hydrochloride monohydrate). TEPMETKO belongs to anticancer medicines called mesenchymal epithelial transition (MET) tyrosine kinase inhibitors.

TEPMETKO has provisional approval to treat adults with non-small cell lung cancer (NSCLC) that has spread to other parts of the body or is advanced, and whose tumours have mesenchymal epithelial transition (MET) exon 14 skipping alterations.

The alterations in the MET gene can lead to a dysfunctional protein which can lead to uncontrolled cell growth and cancer. By blocking this dysfunctional protein, TEPMETKO may slow or stop the cancer from growing. It may also help to shrink the cancer

2. What should I know before I use TEPMETKO?

Warnings

Do not use TEPMETKO if:

 you are allergic to tepotinib, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

 have or have had any new or worsening symptoms indicative of inflammation of the lungs, e.g. sudden breathing difficulties, cough or fever