

TEPMETKO®

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 TEPMETKO?

TEPMETKO contains the active ingredient tepotinib (as hydrochloride monohydrate). TEPMETKO is used 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.

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

2. What should I know before I use TEPMETKO?

Do not use if you have ever had an allergic reaction to TEPMETKO 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 have a baby or are breastfeeding.

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

3. What if I am taking other medicines?

Some medicines may interfere with TEPMETKO 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 do I use TEPMETKO?

- Recommended dose: 450 mg (two tablets) orally once daily with food.
- Swallow the tablet(s) whole. Do not break, crush or chew the tablet(s).

More instructions can be found in Section [4. How do I use TEPMETKO?](#) in the full CMI.

5. What should I know while using TEPMETKO?

Things you should do	<ul style="list-style-type: none">• Tell your doctor or pharmacist if you are about to start on taking any new medicines while using TEPMETKO• Tell your doctor if you become pregnant while using TEPMETKO
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly without telling your doctor.• Do not change the dose unless your doctor tells you to.• Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
Driving or using machines	<ul style="list-style-type: none">• You should take special care when driving and using machines as you may feel unusually tired while taking TEPMETKO.

Looking after your medicine

- Store TEPMETKO tablets below 30°C in the original package to protect from moisture.
- Keep this medicine where children cannot reach it.
- Do not use the medicine after the expiry date on the label

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

6. Are there any side effects?

Most common adverse reactions were swelling in your face or other parts of the body, nausea, vomiting, diarrhoea. Serious side effects may include sudden difficulty in breathing with cough or fever, dark-coloured urine, yellow skin and eyes, loss of appetite. 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. 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.

TEPMETKO®

Active ingredient: tepotinib (*as hydrochloride monohydrate*)

This medicine has **provisional approval** in Australia to treat adult patients 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 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.

Consumer Medicine Information (CMI)

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?](#)
- [7. Product details](#)

1. Why am I using TEPMETKO?

TEPMETKO contains the active ingredient tepotinib (as hydrochloride monohydrate). TEPMETKO belongs to anti-cancer 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
- have or have had liver problems
- take any medicines for any other conditions (see [Section 3. What if I am taking other medicines?](#)).

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

Tell your doctor if you:

- are pregnant or if you (male or female) are planning to have a baby. TEPMETKO can harm your unborn baby.
 - Females who are able to become pregnant:
 - Your doctor may do a pregnancy test before you start treatment with TEPMETKO.
 - You should use effective birth control (contraception) during treatment and for at least one week after the final dose of TEPMETKO. Talk to your doctor about birth control methods that may be right for you.
 - Males with female partners who are able to become pregnant should use effective birth control during treatment with TEPMETKO and for at least one week after your final dose.
- are breastfeeding or intend to breastfeed. It is not known if TEPMETKO passes into your breast milk. You should not breastfeed during treatment and for at least one week after your final dose.

Use in children and adolescents

The effectiveness of TEPMETKO in children and adolescents under the age of 18 years has not been established.

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 TEPMETKO and should be avoided during TEPMETKO treatment.

These include:

- rifampicin to treat bacterial infections including tuberculosis
- phenytoin and carbamazepine to treat epilepsy
- St. John's Wort, a herbal medicine used to treat anxiety or depression
- ketoconazole or itraconazole to treat fungal infections

Some medicines may not work properly if you are taking TEPMETKO.

These include:

- digoxin to treat heart conditions
- metformin to treat high blood glucose levels

You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor may need to supervise their effects more closely.

Your doctor will have more information on medicines to be careful with or to avoid whilst using TEPMETKO.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TEPMETKO.

4. How do I use TEPMETKO?

How much to use/take TEPMETKO

Your doctor will tell you how many tablets you need to take each day.

The usual dose of TEPMETKO is 450 mg (two tablets) taken orally once per day at the same time.

Your doctor may change your dose during treatment. Follow the instructions provided by your doctor.

Do not change the dose or stop using TEPMETKO unless your doctor tells you to.

When to use/take TEPMETKO

TEPMETKO should be taken once per day at about the same time each day.

How to take TEPMETKO

Follow all directions given to you by your doctor or pharmacist carefully.

You should take TEPMETKO tablet(s) with food. Do not chew, crush or split the tablet(s).

If you forget to use TEPMETKO

TEPMETKO should be used regularly at the same time each day. If you miss your dose at the usual time, take your recommended dose as soon you remember.

If it is almost time for your next dose (e.g. within 8 hours), skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of you getting an unwanted side effect.

If you use too much TEPMETKO

If you think that you have used too much TEPMETKO, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using TEPMETKO?

Things you should do

Call your doctor straight away if you:

- are about to start on taking any new medicines.
- become pregnant during treatment with TEPMETKO.
- experience allergic reactions, including shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.
- experience any side effects as listed in Section 6. Your doctor may keep or change your dose during treatment. If your condition worsens, your doctor may stop your treatment temporarily or permanently depending on your condition.

Remind any doctor, dentist or pharmacist you visit that you are using TEPMETKO.

TEPMETKO may interfere with the result of some laboratory tests.

Things you should not do

- Do not stop using this medicine suddenly unless your doctor tells you to.
- Do not give TEPMETKO to anyone else, even if their conditions seem similar to yours.

- Do not change the dose without checking with your doctor.

Driving or using machines

You should take special care when driving and using machines as you may feel unusually tired while taking TEPMETKO.

Looking after your medicine

Keep your tablets in the pack in a dry cool place where the temperature stays below 30°C. Do not remove the tablets from the carton pack.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Swelling in your face or other parts of your body• Diarrhoea• Nausea• Vomiting• Abdominal pain• Constipation• Fatigue or tiredness• Abnormal kidney or liver blood test results	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● Abnormal blood test results for digestive enzymes (amylase, lipase) ● Reduced protein levels in the blood ● Shortness of breath, chest pain and cough 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● Sudden difficulty in breathing with a cough or fever. This may be a sign of inflamed lungs called interstitial lung disease. 	<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>
<ul style="list-style-type: none"> ● Signs of liver problems, including dark-coloured urine, yellow skin and eyes, light-coloured stools, confusion, tiredness, loss of appetite, aching or tenderness on the right 	<p>Call your doctor straight away. Your doctor will do blood tests to check your liver function.</p>

Serious side effects	What to do
side of your stomach area, weakness and swelling in your stomach area.	

Depending on the severity of your condition, your doctor may reduce your dose or ask you to stop the treatment temporarily or permanently.

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 TEPMETKO contains

Active ingredient (main ingredient)	Tepotinib (as hydrochloride monohydrate)
Other ingredients (inactive ingredients)	Mannitol, colloidal anhydrous silica, crospovidone, magnesium stearate, microcrystalline cellulose Film coating: Hypromellose, lactose monohydrate, macrogol 3350, triacetin, red iron oxide, titanium dioxide
Potential allergens	Not applicable

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

What TEPMETKO looks like

TEPMETKO is white-pink, oval, biconvex film-coated tablet with embossment "M" on one side and plain on the other side (Aust R 370977). Each pack contains 60 tablets.

Who distributes TEPMETKO

Merck Healthcare Pty Ltd

Suite 1, Level 1, Building B

11 Talavera Road, Macquarie Park

NSW 2113

Australia

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