

Your guide to **TEPMETKO**[®] (tepotinib)

The ONLY Approved Once-Daily Oral Treatment*

For eligible individuals living with metastatic non-small cell lung cancer (mNSCLC) with *MET* exon 14 skipping (*MET*ex14) alterations†

How TEPMETKO was granted accelerated approval

TEPMETKO has been approved under accelerated approval based on a clinical trial that measured how many people with mNSCLC responded and how long they responded. Continued approval may depend on benefit demonstrated in ongoing clinical trials.

INDICATION

What is TEPMETKO used for?

TEPMETKO[®] (tepotinib) is a prescription medicine used to treat adults with non-small cell lung cancer (NSCLC) that:

- has spread to other parts of the body (metastatic), and
- whose tumors have specific abnormalities in the mesenchymal epithelial transition (*MET*) gene. Your healthcare provider will perform a test to make sure that TEPMETKO is right for you.

It is not known if TEPMETKO is safe and effective in children.

SELECTED SAFETY INFORMATION

What Warnings should I know about TEPMETKO?

TEPMETKO may cause severe or life-threatening swelling (inflammation) of the lungs during treatment that can lead to death. Tell your healthcare provider right away if you develop any new or worsening symptoms of lung problems, including: trouble breathing, shortness of breath, cough, or fever.

*Recommended dose is 450 mg once daily with food; please see pages 8-9 to learn more.

†*MET*ex14 skipping is a biomarker representing specific abnormal changes in the *MET* gene that may drive cancer growth.

All images are actor portrayals.

Please see Important Safety Information on pages 6-7.

Please click for full [Prescribing Information](#) and [Patient Information](#) or visit tepmetko.com



About metastatic non-small cell lung cancer (mNSCLC) with *MET*ex14



What is *MET*ex14?

Certain gene abnormalities can drive cancer growth in mNSCLC. For example, *MET*ex14 are specific changes in the mesenchymal-epithelial transition (*MET*) gene in which part of the gene product is not made. Some of these gene alterations, such as *MET*ex14, can be detected by tests as “biological markers” (or “biomarkers”), which may help your doctor predict whether a treatment option would be beneficial for you.



How common is *MET*ex14 in NSCLC?

Based on 2022 estimates in the United States, approximately 199,000 individuals have NSCLC. Of those individuals, approximately 3% to 4% (about 6,000 to 8,000) may have the biomarker *MET*ex14.

*MET*ex14=mesenchymal-epithelial transition exon 14 skipping. *MET*ex14 is a biomarker representing specific abnormal changes in the *MET* gene that can drive cancer growth.

Please see Important Safety Information on pages 6-7.

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The Only Approved Once-Daily Oral Treatment*

For eligible individuals living with mNSCLC with *MET*ex14

Why have you been prescribed **TEPMETKO**?

After your healthcare team completed biomarker testing,[†] the results showed that you have mNSCLC with *MET*ex14, a biomarker found in some individuals with mNSCLC. Your doctor prescribed **TEPMETKO** because it's the ONLY once-daily oral treatment proven to help people like you.

How does **TEPMETKO** work?

TEPMETKO is a targeted treatment designed to help shrink or slow the growth of certain tumors. It works by binding to the *MET* protein and blocking signaling to help prevent the production of other cancer-driving proteins.

*Recommended dose is 450 mg once daily with food; please see pages 8-9 to learn more.

[†]Biomarker testing can help identify if you have a particular biomarker associated with your mNSCLC, allowing your doctor to determine the best treatment option for your cancer.



TEPMETKO was studied in 2 different groups of individuals with mNSCLC who had *METex14*

- Individuals who did not receive treatment for their mNSCLC (**not previously treated**) before taking TEPMETKO
- Individuals who did receive treatment for their mNSCLC (**previously treated**) before taking TEPMETKO

The clinical trial measured:



Overall response rate*:
the percentage of people who saw a decrease in the size or number of their tumors



Duration of response†:
how long their tumor responded to treatment without progressing

Common side effects seen in the clinical trial included: swelling in the face or other parts of the body, tiredness, nausea, diarrhea, muscle and joint pain, and shortness of breath.

*Measures the change in the size of a tumor or the number of tumors. In some people, the tumors become smaller or the number of tumors decrease. Tumors can also disappear (not the same as a cure).

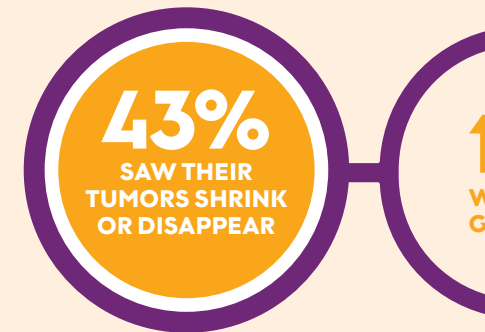
†The measurement of time that a tumor continues to respond to treatment without growing or spreading.

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TEPMETKO was proven to help shrink or slow the growth of tumors for some study participants with mNSCLC with *METex14*

69 study participants **NOT PREVIOUSLY TREATED** before taking TEPMETKO



10.8 months
WITHOUT THEIR CANCER
GROWING OR SPREADING*

- 67% responded to treatment for 6 months or more
- 30% responded to treatment for 9 months or more

*Half of the study participants who responded to treatment continued to respond for longer than 10.8 months and half responded for less than 10.8 months.

83 study participants **PREVIOUSLY TREATED** before taking TEPMETKO



11.1 months
WITHOUT THEIR CANCER
GROWING OR SPREADING†

- 75% responded to treatment for 6 months or more
- 50% responded to treatment for 9 months or more

†Half of the study participants who responded to treatment continued to respond for longer than 11.1 months and half responded for less than 11.1 months.

TEPMETKO is not a cure. The results represent study participants in the clinical trial, and not all study participants will experience the same results.

Important Safety Information

What is TEPMETKO used for?

TEPMETKO is a prescription medicine used to treat adults with non-small cell lung cancer (NSCLC) that:

- has spread to other parts of the body (metastatic), and
- whose tumors have specific abnormalities in the mesenchymal epithelial transition (*MET*) gene. Your healthcare provider will perform a test to make sure that TEPMETKO is right for you. It is not known if TEPMETKO is safe and effective in children.

What Warnings should I know about TEPMETKO?

TEPMETKO may cause severe or life-threatening swelling (inflammation) of the lungs during treatment that can lead to death. Tell your healthcare provider right away if you develop any new or worsening symptoms of lung problems, including: trouble breathing, shortness of breath, cough, or fever.

TEPMETKO may cause abnormal liver blood test results. Your healthcare provider will do blood tests to check your liver function before you start treatment and during treatment with TEPMETKO. Tell your healthcare provider

right away if you develop any signs and symptoms of liver problems, including: your skin or the white part of your eyes turns yellow; dark or “tea colored” urine; light-colored stools (bowel movements); confusion; tiredness; loss of appetite for several days or longer; nausea and vomiting; pain, aching, or tenderness on the right side of your stomach-area (abdomen); weakness; or swelling in your stomach-area.

TEPMETKO can cause harm to an unborn baby in pregnant women.

Females who are able to become pregnant:

- Your healthcare provider may do a pregnancy test before you start treatment with TEPMETKO.
- You should use effective birth control (contraception) during treatment and for 1 week after the final dose of TEPMETKO. Talk to your healthcare provider 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 1 week after the final dose of TEPMETKO.

What should I tell my health care provider?

Tell your healthcare provider about all of your medical conditions, including if you:

- have or have had lung or breathing problems other than your lung cancer
- have or have had liver problems
- are pregnant or plan to become pregnant. TEPMETKO can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if TEPMETKO passes into your breast milk. Do not breastfeed during treatment and for 1 week after the final dose of TEPMETKO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the side effects of TEPMETKO?

The most common side effects of TEPMETKO include: swelling in your face or other parts of your body; tiredness; nausea; diarrhea; muscle and joint pain; and shortness of breath. Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with TEPMETKO if you develop serious side effects

during treatment. These are not all of the possible side effects of TEPMETKO. Call your doctor for medical advice about side effects.

You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch.



SWELLING
in your face or
other parts of
your body



TIREDNESS



NAUSEA



DIARRHEA



**MUSCLE AND
JOINT PAIN**



**SHORTNESS
OF BREATH**

Taking TEPMETKO® (tepotinib)

TEPMETKO should be taken exactly as your doctor prescribed



Take TEPMETKO once a day with food.

Do not change your dose or stop taking TEPMETKO unless recommended by your doctor



Swallow whole.

Do not chew, crush, or split tablets



Stay on schedule.

Take your dose at about the same time each day



What if I miss a dose of TEPMETKO?

Remember—keeping to a routine dosing schedule can help keep your treatment on track.

- **If you miss a dose**, take it as soon as you remember. If your next dose is due within 8 hours, skip the missed dose and take your next dose at your regular scheduled time
- **If you vomit after taking a dose** of TEPMETKO, take your next dose at your regular scheduled time

How should I store/handle TEPMETKO?



Store TEPMETKO tablets in their original packaging at room temperature between 68°F to 77°F (20°C to 25°C)



TEPMETKO tablets come in blister cards with child-resistant blister foil



Keep TEPMETKO and all medicines out of the reach of children

Please see Important Safety Information on pages 6-7.

Please click for full [Prescribing Information](#) and [Patient Information](#) or visit tepmetko.com

Questions for your healthcare team

You and your loved ones will likely have questions about your treatment. Here are some questions that you might want to ask your healthcare team at your next appointment. Feel free to write down your doctor's answers in the blank spaces below.

Remember—being open and honest about your questions and concerns can help you get the most out of your time together. Don't hesitate to ask for more information.

Is there anything I should do before treatment?

What can I expect during treatment?

How will I know if TEPMETKO® (tepotinib) is working?

What are common side effects of the medicine? Do you have any tips to help manage them?
Whom do I contact if I have side effects?

Are there any support resources available or programs or groups I can join?

What financial resources or assistance is available?

Write down any other questions you may have:

Patient access and reimbursement support

The **EMD Serono Oncology Navigation Center® (ONC)** is a patient access and reimbursement support program available to help eligible patients gain appropriate access to TEPMETKO® (tepotinib) in the United States.*

Program provides:

- Reimbursement support
- Bridge program for new patients with insurance delays
- Co-pay assistance for privately insured patients
- Patient assistance program/free drug program for eligible patients



Our ONC Access Navigators are committed to helping eligible patients access TEPMETKO

Please contact us if you have any questions or fax a completed ONC Enrollment Form to verify patient-specific coverage or request assistance. **Enrollment forms and complete program information are available through [OncNavigationCenter.com](https://www.oncnavigationcenter.com).**

[OncNavigationCenter.com](https://www.oncnavigationcenter.com)

Phone: 1-844-662-3631 (844-ONC-EMD1)

Fax: 844-501-0062

Monday–Friday: 8:00 AM–8:00 PM Eastern Time

***Additional program rules and restrictions or conditions may apply.**

EMD Serono, Inc. does not guarantee coverage and/or reimbursement for TEPMETKO. Coverage, coding, and reimbursement policies vary significantly by payer, patient, and setting of care. Actual coverage and reimbursement decisions are made by individual payers following the receipt of claims. Patients and healthcare professionals should always verify coverage, coding, and reimbursement guidelines on a payer and patient-specific basis.

Resources you might find helpful

Learn more about biomarkers and comprehensive biomarker testing for mNSCLC



[lungevity.org](https://www.lungevity.org)



[metcrusaders.org](https://www.metcrusaders.org)

The organizations listed above are independent nonprofit organizations. Their inclusion here does not imply endorsement of TEPMETKO® (tepotinib) or EMD Serono, Inc.

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