

PATIENT INFORMATION

TEPMETKO® (tep-MET-co)

(tepotinib)

tablets, for oral use

What is the most important information I should know about TEPMETKO?

TEPMETKO may cause serious side effects, including:

- **Lung problems.** 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
 - fever

See “What are possible side effects of TEPMETKO?” for more information about side effects.

What is TEPMETKO?

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 an abnormal 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.

Before you take TEPMETKO, 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
- have or have had pancreatic problems
- are pregnant or plan to become pregnant. TEPMETKO can harm your unborn baby.

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 last 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 (contraception) during treatment with TEPMETKO and for 1 week after the last dose of TEPMETKO.

- 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 last dose of TEPMETKO.

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

How should I take TEPMETKO?

- Take TEPMETKO exactly as your healthcare provider tells you to. Do not change your dose or stop taking TEPMETKO unless your healthcare provider tells you to.
- Take TEPMETKO 1 time a day with food.
- Take your dose of TEPMETKO at about the same time each day.
- Swallow TEPMETKO tablets whole. **Do not chew, crush or split the tablets.**

If you cannot swallow TEPMETKO tablets whole:

- Place your prescribed dose of TEPMETKO tablets in a glass that contains 30 mL (1 ounce) of non-carbonated water. **Do not** use or add any other liquids.
- Stir the TEPMETKO tablets and water until the TEPMETKO tablets are in small pieces (the tablets will not completely dissolve). **Do not** crush TEPMETKO tablets.
- Drink the TEPMETKO and water mixture right away or within 1 hour. Make sure to swallow the mixture. **Do not** chew pieces of the tablet.
- Add another 30 mL of non-carbonated water to the glass and drink it right away to get your full dose of TEPMETKO.

If you have a nasogastric (NG) tube that is 8 French gauge or larger:

- Follow the same instructions for mixing TEPMETKO tablets in a glass that contains 30 mL of non-carbonated water.
- **Do not** use or add any other liquids.
- Stir the TEPMETKO tablets and water until the TEPMETKO tablets are in small pieces (the tablets will not completely dissolve). **Do not** crush TEPMETKO tablets.
- Give the TEPMETKO tablet and water mixture using the NG tube manufacturer instructions right away or within 1 hour.
- Pieces of the tablet may remain in the glass. Right away, add 30 mL of non-carbonated water into the glass. Give the water and any remaining TEPMETKO through the NG tube right away to make sure that all of the medicine is given. Repeat this step. This will help to ensure that no medicine is left in the glass or syringe and the full prescribed dose of TEPMETKO is given.
- If you miss a dose of TEPMETKO, 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.

What are the possible side effects of TEPMETKO?

TEPMETKO may cause serious side effects, including:

- See “**What is the most important information I should know about TEPMETKO?**”
- **Liver problems.** 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
 - swelling in your stomach-area
- **Pancreas problems.** TEPMETKO may cause increases in your blood amylase and lipase levels that may indicate a problem with your pancreas. Your healthcare provider will do blood tests to check your pancreatic function before you start treatment and during treatment with TEPMETKO. Tell your healthcare provider right away if you develop any signs and symptoms of pancreas problems, including:
 - upper stomach (abdominal) pain that may spread to your back and get worse with eating
 - weight loss
 - nausea
 - vomiting

The most common side effects of TEPMETKO include:

- swelling in your face or other parts of your body
- nausea
- tiredness
- muscle and joint pain
- diarrhea
- shortness of breath
- loss of appetite
- rash
- changes in certain blood tests

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.

How should I store TEPMETKO?

- Store TEPMETKO at room temperature between 68°F to 77°F (20°C to 25°C).
- TEPMETKO tablets come in blister cards with a child-resistant blister foil.
- Store TEPMETKO in original package.

Keep TEPMETKO and all medicines out of the reach of children.

General information about the safe and effective use of TEPMETKO.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use TEPMETKO for a condition for which it was not prescribed. Do not give TEPMETKO to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about TEPMETKO that is written for health professionals.

What are the ingredients in TEPMETKO?

Active ingredient: tepotinib

Inactive ingredients: mannitol, microcrystalline cellulose, crospovidone, magnesium stearate, and colloidal silicon dioxide.

Tablet coating: hypromellose, titanium dioxide, lactose monohydrate, polyethylene glycol, triacetin, and red iron oxides.

Manufactured for: EMD Serono, Inc., Rockland, MA 02370, U.S.A.

TEPMETKO is a trademark of Merck KGaA, Darmstadt, Germany.

Product of Germany.

For more information, call toll-free 1-844-662-3631 or go to www.TEPMETKO.com.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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