

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

PrTEPMETKO™
Tepotinib Tablets

Read this carefully before you start taking **TEPMETKO** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TEPMETKO**.

What is TEPMETKO used for?

See the following boxed text:

For the following indication TEPMETKO has been approved *with conditions* (NOC/c). This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the drug works the way it should. For more information, talk to your healthcare professional.

- TEPMETKO is used to treat a type of lung cancer called non-small cell lung cancer (NSCLC). It is used in adults:
 - whose cancer has spread to other parts of the body or is advanced and cannot be removed by surgery, and
 - whose tumours have a change (abnormality) in the "MET" gene (known as the mesenchymal epithelial transition gene).

Your healthcare professional will perform a test to make sure that TEPMETKO is right for you.

What is a Notice of Compliance with Conditions (NOC/c)?

A Notice of Compliance with Conditions (NOC/c) is a type of approval to sell a drug in Canada.

Health Canada only gives an NOC/c to a drug that treats, prevents, or helps identify a serious or life-threatening illness. The drug must show promising proof that it works well, is of high quality, and is reasonably safe. Also, the drug must either respond to a serious medical need in Canada, or be much safer than existing treatments.

Drug makers must agree in writing to clearly state on the label that the drug was given an NOC/c, to complete more testing to make sure the drug works the way it should, to actively monitor the drug's performance after it has been sold, and to report their findings to Health Canada.

Serious Warnings and Precautions

- TEPMETKO can cause serious side effects, including:
 - **Liver problems (increased liver enzymes):** Increased liver enzymes are very common with TEPMETKO. Liver problems may sometimes be serious and can lead to death. Your healthcare professional will run blood tests to check your liver before and during treatment.
 - **Interstitial lung disease / Pneumonitis:** TEPMETKO may cause inflammation or scarring of the lungs that can lead to death. Your healthcare professional will monitor you for lung problems. Tell your healthcare professional right away if you develop new or worsening symptoms of lung problems, including: trouble breathing, shortness of breath, cough, or fever. Symptoms may be similar to those from lung cancer.
- TEPMETKO can harm your unborn baby if you take it while you are pregnant.
- Only a doctor who has experience treating cancer should treat you with this drug.

How does TEPMETKO work?

TEPMETKO belongs to a group of cancer medicines called MET tyrosine kinase inhibitors. A change in the MET gene can produce a protein that causes cancer cells to grow. TEPMETKO works by blocking this protein. This may slow or stop the cancer from growing. It may also help to shrink the cancer.

What are the ingredients in TEPMETKO?

Medicinal ingredient: tepotinib (as tepotinib hydrochloride)

Non-medicinal ingredients: colloidal silicon dioxide, crospovidone, hypromellose, lactose monohydrate, magnesium stearate, mannitol, microcrystalline cellulose, polyethylene glycol, red iron oxides (E172), titanium dioxide, triacetin.

TEPMETKO comes in the following dosage forms:

Tablets, 225 mg tepotinib (as tepotinib hydrochloride)

Do not use TEPMETKO if:

- you are allergic to tepotinib or any of the other ingredients of this medicine. Talk to your healthcare professional if you are not sure.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TEPMETKO. Talk about any health conditions or problems you may have, including if you:

- have or have had problems with your kidney
- have or have had problems with your liver
- have an allergy to lactose. This is because TEPMETKO contains lactose.

Other warnings you should know about:

Pregnancy and breastfeeding:

Female patients:

- If you are pregnant, able to get pregnant or think you are pregnant, there are specific risks you should discuss with your healthcare professional.
- You should not take TEPMETKO if you are pregnant. It can harm your unborn baby.
- If you are able to become pregnant:
 - Your healthcare professional should do a pregnancy test before you start treatment with TEPMETKO.
 - Avoid becoming pregnant while you are taking TEPMETKO. Use effective birth control during treatment and for 1 week after your final dose of TEPMETKO. Talk to your healthcare professional about birth control methods that may be right for you during this time.
 - Tell your healthcare professional right away if you become pregnant or think you may be pregnant during treatment with TEPMETKO
- Do NOT breastfeed during treatment and for 1 week after your final dose of TEPMETKO. It is not known if TEPMETKO passes into your breast milk. Talk to your healthcare professional about the best way to feed your baby during this time.

Male patients with female partners who can become pregnant:

- You should not father a child while taking TEPMETKO. It may harm your unborn baby.
- Use condoms each time you have sex while taking TEPMETKO and for 1 week following your final dose.
- If your partner becomes pregnant while you are taking TEPMETKO, tell your healthcare professional right away.

Fertility:

It is unknown whether TEPMETKO may affect your fertility. No human studies on fertility have been performed. Talk to your healthcare professional if you have questions about this.

Driving and using machines:

Before you do tasks that require special attention, wait until you know how you respond to TEPMETKO.

Children and adolescents: TEPMETKO is NOT approved for use in children and adolescents under the age of 18 years.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with TEPMETKO:

- Carbamazepine and phenytoin – used to treat epilepsy
- Rifampicin – used to treat lung disease
- St. John's Wort (*hypericum perforatum*) – a herbal medicine, used to treat depression
- Digoxin – used to treat heart conditions
- Itraconazole – used to treat fungal infections

How to take TEPMETKO:

- Take TEPMETKO exactly as your healthcare professional tells you to take it. Check with your doctor, pharmacist or nurse if you are not sure.
- Do NOT change your dose or stop taking it unless your healthcare professional tells you to.
- Take TEPMETKO 1 time a day with food.
- Take it at about the same time each day
- If your daily dose consists of more than one tablet, take both tablets together at the same time as a single dose.
- Swallow tablets whole. Do NOT chew, crush or split tablets.

Usual dose:**Usual adult dose:**

450 mg (two 225 mg tablets) by mouth once a day.

Your healthcare professional may change your dose, interrupt, or permanently stop treatment with TEPMETKO. This may happen if you develop certain side effects or if your disease gets worse.

Overdose:

If you think you have taken too much TEPMETKO, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

- If you miss a dose and it is more than 8 hours until your next dose, take the missed dose with food as soon as you remember. Continue with your next dose at your regular time.
- If it is within 8 hours of your next dose, skip the missed dose. Wait and take your next dose at your regular time. Do NOT take a double dose to make up for the missed dose.
- If you vomit after taking TEPMETKO, wait and take the next dose at your next scheduled time. Do not take an extra dose.

What are possible side effects from using TEPMETKO?

These are not all the possible side effects you may feel when taking TEPMETKO. If you experience any side effects not listed here, contact your healthcare professional.

Side effects of TEPMETKO include:

- swelling of your face or other parts of your body
- fatigue, weakness, dizziness, headache
- nausea, vomiting
- diarrhea, constipation
- stomach pain
- decreased appetite
- muscle, bone or joint pain
- fever
- rash, itching

TEPMETKO can cause abnormal blood test results. Your healthcare professional will perform blood tests before and during your treatment. Your doctor will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Liver problems (increased liver enzymes): loss of appetite, nausea, vomiting, yellowing of your skin and/or the white part of your eyes (jaundice), dark “tea-coloured” urine, confusion, sleepiness, weakness, pain on the upper right side of stomach, swelling in your stomach area, light-coloured stools (bowel movements)		X	
Pleural effusion (fluid around the lungs): chest pain, difficult or painful breathing, cough		X	
Pneumonia (infection in the lungs): chest pain when you breath or cough, confusion, cough which may produce phlegm, fatigue, fever, sweating, severe shivering with chills, nausea, vomiting or diarrhea, shortness of breath		X	
COMMON			
Acute kidney injury (severe kidney problems): confusion; itchiness or rashes; puffiness in your face and hands; swelling in your feet or ankles; urinating less or not at all; weight gain		X	
Interstitial lung disease / Pneumonitis (inflammation or scarring of the lungs): new or worsening lung problems, including: trouble breathing, shortness of breath, cough, or fever		X	
Severe swelling, including generalized edema (swelling affecting the whole body)		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at room temperature between 15 to 30°C. Keep in the original package to protect from moisture.

Keep out of reach and sight of children.

If you want more information about TEPMETKO:

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>) or the EMD Serono website (<http://www.emdserono.ca>).

This leaflet was prepared by EMD Serono, a Division of EMD Inc., Canada.

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