TEPMETKO™ 225MG FILM-COATED TABLETS

Tepotinib 225 mg (equivalent to 250 mg tepotinib hydrochloride hydrate)

What is in this leaflet

What TEPMETKO is used for

TEPMETKO contains the active substance tepotinib. It belongs to a group of medicines called protein kinase inhibitors which are used to treat cancer.

TEPMETKO is used in adults to treat a type of lung cancer, called non-small cell lung cancer, that has certain abnormal changes in the mesenchymal-epithelial transition factor gene (MET) and which has spread and/or cannot be removed by surgery.

Your doctor will perform a test to check if your cancer has a change in the MET gene to make sure that TEPMETKO is right for you.

How TEPMETKO works

TEPMETKO is a kinase inhibitor that targets MET, including variants with exon 14 skipping alterations.

The changes in the MET gene can make an abnormal protein which can then cause uncontrolled cell growth and cancer. By blocking this abnormal protein TEPMETKO may slow or stop the cancer from growing. It may also help to shrink the cancer.

Before you use TEPMETKO

When you must not use it

Do not take TEPMETKO:

- if you are allergic to tepotinib or any of the other ingredients of TEPMETKO (listed in excipients)
- if you are pregnant or suspect you are pregnant, unless advised by your doctor. TEPMETKO may harm the unborn baby.
- if you are a child or adolescent under the age of 18 years.

Before you start to use it

Talk to your doctor or pharmacist before taking TEPMETKO if any of the following apply to you:

- if you have or have had any other lung problems.
- if you have or have had liver problems.
- if you are pregnant or plan to become pregnant.
- if you are breastfeeding.

Tell your doctor or pharmacist immediately if you develop any new or worsening symptoms during treatment. TEPMETKO may cause sudden breathing difficulties that may be associated with fever and cough.

Your doctor will take blood tests before and regularly during treatment with TEPMETKO. Based on the results, your doctor may decide to interrupt your treatment, reduce your TEPMETKO dose or stop treatment permanently.

Taking other medicines

Tell your doctor if you are using, have recently used or might use any other medicines.

TEPMETKO may affect how well the following medicines work and/or increase side effects of these medicines:

- digoxin – used to treat irregular heartbeat or other heart problems
- metformin – used to treat diabetes mellitus.

How to take TEPMETKO

How much to take

The recommended dose is 450 mg TEPMETKO (2 tablets) taken once daily. In case of side effects, your doctor may advise you to reduce the dose to 1 tablet daily or interrupt the treatment for some days or stop treatment permanently.

When to use it

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Swallow the tablets whole (without crushing or chewing). Take the tablets with food or shortly after a meal.

If you have trouble swallowing the tablets, you can mix them in water:

- Put the tablets in a glass.
- Add 30 mL of still (non-fizzy) water – do not use any other liquids.
- Stir the water thoroughly until the tablet breaks up into very small pieces - the tablet will not completely dissolve.
- Drink immediately. Do not chew the pieces of tablet.
- If needed, you can drink the liquid within one hour, after stirring again.
- To make sure you have taken all of the medicine, rinse the glass thoroughly with another 30 mL of water and drink it.

How long to use it

Do not stop taking TEPMETKO unless you have discussed with your doctor or your doctor tells you to stop.

If you forget to use it

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

If you use too much

Symptoms of overdose with TEPMETKO are not known. If you have taken more TEPMETKO than you should, or if someone else has taken your medicine, contact a doctor or hospital for advice. Medical treatment may be necessary.

While you are using TEPMETKO

Things you must do

If you are female and are of childbearing age, you should use an effective method of contraception to avoid becoming pregnant during TEPMETKO treatment and for at least

1 week after the last dose. Talk to your doctor if you take hormonal contraceptives (e.g. "the pill"). You need a second method of contraception during TEPMETKO treatment and for at least 1 week after the last dose.

If you are male, you should use barrier contraception to prevent your partner from getting pregnant, whilst you are treated with TEPMETKO and for at least 1 week after the last dose.

Things you must not do
It is not known whether TEPMETKO may pass to the baby via breast milk. Do not breast-feed during treatment with TEPMETKO and for at least 1 week after the last dose.

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

Side effects

Serious side effects

Contact your doctor immediately for any of the following:
- if you develop any new or worsening symptoms such as sudden breathing difficulties, shortness of breath, cough or fever. These may be symptoms of a serious lung condition (interstitial lung disease) which needs immediate medical attention. This side effect is common (may affect up to 1 in 10 people).
- if you develop yellow discolouration of the skin and eyes (jaundice), darkening of the urine, light-coloured stools (faeces), loss of appetite, nausea or vomiting, pain on the upper right side of your stomach area. These are symptoms and signs of liver problems.

Other side effects

Very common side effects (may affect more than 1 in 10 people)
- Swelling caused by fluid build-up in the body (oedema)
- Feeling sick (nausea)
- Being sick (vomiting)
- Diarrhoea
- Abdominal pain
- Constipation
- Fatigue or tiredness
- Higher than normal blood levels of creatinine
- Reduced protein levels in the blood
- Higher than normal blood levels of a certain liver enzyme (alanine aminotransferase)
- Higher than normal blood levels of certain liver enzymes (aspartate aminotransferase, alkaline phosphatase)
- Higher than normal blood levels of amylase
- Higher than normal blood levels of lipase

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of TEPMETKO

Storage
Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

Store below 30°C. Store all items in original outer packaging, remove only prior to administration.

Disposal
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product description

What it looks like
TEPMETKO film-coated tablets are white-pink, oval and biconvex with embossment ‘M’ on one side and plain on the other side. Each pack contains 60 tablets in blisters.

Ingredients

Active Ingredient
tepotinib (as hydrochloride hydrate)

Excipients
Tablet core
- mannitol
- colloidal anhydrous silica
- crospovidone
- magnesium stearate
- microcystalline cellulose

Film-coating
- hypromellose
- lactose monohydrate
- macrogol
- triacetin
- red iron oxides (E172)
- titanium dioxide

MAL Number
MAL24126005AZ

Manufacturer
Merck Healthcare KGaA
Frankfurter Strasse 250
64293 Darmstadt Germany

Product Registration Holder
Merck Sdn Bhd (178145-V)
B-23A-1, Level 23A,
The Ascent Paradigm
No.1, Jalan SS7/26A,
Kelana Jaya,
47301 Petaling Jaya,
Selangor, Malaysia

Date of Revision:
Feb 2026

Serial Number
NPRA (R1) 24/029