Package leaflet: Information for the patient

TEPMETKO 225 mg film-coated tablets
tepotinib

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects which you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What TEPMETKO is and what it 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.

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.

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.

2. What you need to know before you take TEPMETKO

Do not take TEPMETKO
- if you are allergic to tepotinib or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
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 (see section 4). TEPMETKO may cause sudden breathing difficulties that may be associated with fever and cough.

Blood tests
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 tepotinib dose or stop treatment permanently.
Children and adolescents
TEPMETKO is not to be used in children and adolescents under the age of 18 years.

Other medicines and TEPMETKO
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 heart beat or other heart problems
- metformin – used to treat diabetes mellitus

Pregnancy
Do not take TEPMETKO if you are pregnant or suspect you are pregnant, unless advised by your doctor. TEPMETKO may harm the unborn baby.

Contraception
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.

Breast-feeding
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.

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

TEPMETKO contains lactose
TEPMETKO contains 4.15 mg lactose in each tablet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take TEPMETKO

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

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.

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 (about half of a tumblerful) 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.

If you take more TEPMETKO than you should
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.

If you forget to take TEPMETKO
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 vomit after taking a dose of TEPMETKO, take your next dose at your regular time.

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

If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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
<u>Very common side effects (may affect more than 1 in 10 people)</u>
- 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)

Common side effects (may affect up to 1 in 10 people)
- 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

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store TEPMETKO

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 25°C. Store all items in original outer packaging, remove only prior to administration.

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.

6. Contents of the pack and other information

What TEPMETKO contains
- The active substance is tepotinib. Each tablet contains 225 mg tepotinib (as hydrocloride hydrate).
- The other ingredients are mannitol, colloidal anhydrous silica, crospovidone, magnesium stearate and microcrystalline cellulose in the tablet core and hypromellose, lactose monohydrate (see section 2, ‘TEPMETKO contains lactose’), Macrogol, triacetin, red iron oxides (E172) and titanium dioxide in the film-coating.

What TEPMETKO looks like and contents of the pack
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 aluminium/polyvinyl chloride-polyethylene-polyvinylidene chloride-polyethylene-polyvinyl chloride blisters.

Marketing Authorisation Holder
Merck Serono Ltd
5 New Square
Bedfont Lakes Business Park
Feltham
Middlesex
TW14 8HA
UK

Manufacturer
Merck Healthcare KGaA
Frankfurter Strasse 250
64293 Darmstadt
Germany

This leaflet was last revised in 07/2024.

This medicine has been given 'conditional approval'. This means that there is more evidence to come about this medicine. The MHRA will review new information on this medicine at least every year and this leaflet will be updated as necessary.

TW3742641