

Patient leaflet in accordance with the Pharmacists'
Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Tepmetko

Film-coated tablets

Active ingredient:

Each film-coated tablet of Tepmetko contains: tepotinib 225 mg.

Inactive ingredients and allergens in this medicine: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine.

If you have any further questions, consult your doctor or pharmacist.

Keep this leaflet handy, you may need to read it again.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for

Tepmetko is used to treat adults with metastatic non-small cell lung cancer (NSCLC) harbouring a MET tyrosine kinase 14 (METex14) skipping mutation.

Therapeutic group: protein kinase inhibitors.

This mutation in the MET gene can lead to a dysfunctional protein, which can lead to uncontrolled cell growth and cancer. By blocking this dysfunctional protein, Tepmetko may slow or stop the cancer from growing. It may also help to shrink the tumour.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6).

Special warnings about using this medicine

Before treatment with Tepmetko, tell your doctor if:
you have any other diseases or if you have allergies.

Lung or breathing problems

Tepmetko may cause sudden breathing difficulties that may be associated with fever and cough. Talk to your doctor right away, if you develop new symptoms or your current symptoms get worse (see also section 4). Your doctor may prescribe a different medicine and tell you to stop your Tepmetko treatment.

Contraception

Men and women must use effective contraception during treatment with Tepmetko and for at least one week after the last dose. Tepmetko may harm the unborn baby. Talk to your doctor about which contraceptive methods are suitable for you and your partner.

Changes in electrocardiogram (ECG) test

Before and while you are taking Tepmetko, tell your doctor if, after an electrocardiogram (ECG), you have been told that you have a prolonged QT interval.

Children and adolescents

This medicine is not intended for children and adolescents below the age of 18 years.

There is no information about the safety and efficacy of using this medicine in children and adolescents below the age of 18 years.

Tests and follow-up

Before and while you are taking Tepmetko, your doctor will refer you for a liver function test and will adjust your dose as necessary.

Interactions with other medicines

If you are taking or have recently taken other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist.

The following medicines may increase or decrease the effect of Tepmetko:

- carbamazepine or phenytoin - used to treat seizures or fits
- rifampicin - used to treat tuberculosis
- St. John's wort - a herbal medicine used to treat depression
- itraconazole - used to treat fungal infections

Tepmetko may affect how the following medicines work and/or increase their side effects:

- digoxin - used to treat irregular heart rhythm or other heart problems
- metformin - used to treat diabetes mellitus
- dabigatran - used to prevent stroke or venous thrombosis/lung embolism
- rosuvastatin - used to treat high blood lipid levels

If you are taking any of the medicines listed above, or if you are not sure, talk to your doctor or pharmacist before taking Tepmetko.

Using this medicine and food

Swallow the tablets whole with or immediately after food.

Pregnancy and breast-feeding

Do not take Tepmetko if you are pregnant unless advised otherwise by your doctor.

Tepmetko may harm the unborn baby.

You must use an effective method of contraception to prevent pregnancy during Tepmetko treatment and for at least one week after the last dose.

Men must use a reliable barrier method of contraception during treatment with Tepmetko and for at least one week after the last dose, in order to prevent their partner from getting pregnant.

You must stop breast-feeding during treatment with Tepmetko and for at least one week after the last dose.

Driving and using machines

As Tepmetko can cause side effects such as tiredness, nausea, and vomiting, caution is advised when driving vehicles and operating machines.

Important information about some of this medicine's ingredients

If you have been told by your doctor that you have an intolerance to certain sugars, talk to your doctor before taking this medicine.

3. How to use this medicine

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine. The recommended dosage is usually:

2 film-coated tablets of Tepmetko (450 mg) once daily. If side effects occur, your doctor may advise you to reduce the dose to one tablet daily or interrupt the treatment for a few days. Do not exceed the recommended dose.

How to take Tepmetko

Tepmetko is intended for oral use.

Swallow the tablets whole, without chewing, with food or just after a meal.

If you have taken a higher dose

No symptoms of overdose with Tepmetko have been identified.

If you have taken an overdose or if a child has accidentally swallowed some medicine, go to a hospital emergency room immediately and bring the medicine package with you.

If you forget to take the medicine, take it as soon as you remember. However, if your next dose is due within 8 hours, skip the missed dose and take your next dose at your regular time.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not change or stop your treatment without consulting your doctor.

Do not make changes to your prescribed dose yourself. If you think that the effect of the medicine is too weak or too strong, talk to your doctor or pharmacist.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Tepmetko may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Consult your doctor immediately:

Lung or breathing problems: Talk to your doctor right away if you develop new symptoms or if symptoms like sudden breathing difficulties, cough, and fever get worse. These could be signs of a serious lung disease (interstitial lung disease) which require immediate medical attention (common side effect, affects 1-10 in 100 users).

Additional side effects:

Very common side effects (affect more than 1 in 10 users):

swelling caused by fluid build-up in the body (oedema), nausea, diarrhoea, tiredness, loss of appetite, vomiting, higher than normal blood levels of creatinine, shortness of breath, higher than normal liver enzyme levels (ALT/AST), fluid accumulation in the chest with shortness of breath, cough and/or pain, reduced protein levels in the blood.

Common side effects (affect 1-10 in 100 users):

higher than normal blood levels of amylase, lipase, or alkaline phosphatase.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il>

5. How to store the medicine

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store below 25°C. Keep in the original package.
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. This will protect the environment.

6. Additional information

- In addition to the active ingredient, this medicine also contains:
Core: mannitol, microcrystalline cellulose, crospovidone, magnesium stearate, colloidal silicon dioxide

Film-coating: hypromellose, titanium dioxide, lactose monohydrate, polyethylene glycol, triacetin, red iron oxide

- What the medicine looks like and contents of the pack:
Tepmetko film-coated tablets are white-pink, oval and bi-convex with M embossed on one side. Each pack contains 60 tablets packaged in a blister tray.
- Registration holder's name and address: Merck Serono Ltd., 18 Hakishon St., Yavne, 81220.
- Manufacturer's name and address: Merck Healthcare KGaA, Darmstadt, Germany.
- This leaflet was revised in October 2023 according to MOH guidelines.
- Registration number of the medicine in the Ministry of Health's National Drug Registry: 169-25-36977-99