



# Information for the patient

## Teponi 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 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- This leaflet has been written as though the person taking the medicine is reading it. If you are giving this medicine to your child, please replace "you" with "your child" throughout.

#### What is in this leaflet:

1. What Teponi is and what it is used for
2. What you need to know before you take Teponi
3. How to take Teponi
4. Possible side effects
5. How to store Teponi
6. Contents of the pack and other information

#### 1. What Teponi is and what it is used for

##### What Teponi is used for

Teponi contains the active substance Tepotinib.

Teponi is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping alterations

Teponi 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 Teponi is right for you.

##### How Teponi works

Teponi is a kinase inhibitor that targets MET, including valiants with exon 14 skipping alterations. Teponi inhibits hepatocyte growth factor (HGF)-dependent and -independent MET phosphorylation and MET-dependent downstream signaling pathways. Teponi also inhibited melatonin 2 and imidazole 1 receptors at clinically achievable concentrations.

If you have any questions on how Teponi works or why it has been prescribed for you, ask your doctor, pharmacist or nurse.

#### 2. What you need to know before you take Teponi

##### Do not take Teponi if

- you are allergic to Tepotinib or any of the other ingredients of this medicine (listed in section 6).

##### Tests and checks

Select patients for treatment with Teponi based on the presence of MET exon 14 skipping alterations in plasma or tumor specimens. Testing for the presence of MET exon 14 skipping alterations in plasma specimens is recommended only in patients for whom a tumor biopsy cannot be obtained. If an alteration is not detected in a plasma specimen, re-evaluate the feasibility of biopsy for tumor tissue testing.

#### Before you receive Teponi, 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
- are pregnant or plan to become pregnant. Teponi can harm your unborn baby.

#### Females who are able to become pregnant:

- o Your healthcare provider may do a pregnancy test before you start treatment with Teponi.
- o You should use effective birth control (contraception) during treatment and for 1 week after the final dose of Teponi. 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 during treatment with Teponi and for 1 week after the final dose of Teponi.

- are breastfeeding or plan to breastfeed. It is not known if Teponi passes into your breast milk. Do not breastfeed during treatment and for 1 week after the final dose of Teponi.

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

#### Pregnancy and breast-feeding

##### Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not use Teponi during pregnancy since the effect of Teponi on the unborn is not known.

##### Breast-feeding

There are no data regarding the secretion of Teponi or its metabolites in human milk or its effects on the breastfed infant or milk production. Advise women not to breastfeed during treatment with Teponi and for one week after the final dose.

#### Driving, cycling and using machines

Teponi may make you feel dizzy or tired. If this happens, do not drive, cycle or use any tools or machines.

#### 3. How to take Teponi

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

##### How much to take

The recommended dosage of Teponi is 450 mg orally once daily with food until disease progression or unacceptable toxicity.

##### How to take this medicine

Instruct patients to take their dose of Teponi at approximately the same time every day and to swallow tablets whole. Do not chew, crush or split tablets.

##### If you take more Teponi than you should

Talk to your doctor, pharmacist or nurse or go to a hospital straight away. Take the medicine pack and this leaflet with you.

##### If you miss a dose of Teponi

Advise patients not to make up a missed dose within 8 hours of the next scheduled dose.

If vomiting occurs after taking a dose of Teponi, advise patients to take the next dose at the scheduled time.

##### If you stop taking Teponi

Do not stop taking this medicine without talking to your doctor first. It is important to take Teponi for as long as your doctor tells you.

If you are not able to take the medicine as your doctor prescribed talk to your doctor straight away.

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

#### 4. Possible side effects

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

##### Teponi may cause serious side effects, including:

- **Lung problems.** Teponi 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:
  - o trouble breathing
  - o shortness of breath
  - o cough
  - o fever
- **Liver problems.** Teponi 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 Teponi. Tell your healthcare provider right away if you develop any signs and symptoms of liver problems, including:
  - o your skin or the white part of your eyes turns yellow
  - o dark or "tea colored" urine
  - o light-colored stools (bowel movements)
  - o confusion
  - o tiredness
  - o loss of appetite for several days or longer
  - o nausea and vomiting
  - o pain, aching, or tenderness on the right side of your stomach-area (abdomen)
  - o weakness
  - o swelling in your stomach-area

##### The most common side effects of Teponi include:

- swelling in your face or other parts of your body
- tiredness
- nausea
- diarrhea
- muscle and joint pain
- shortness of breath

Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with Teponi if you develop serious side effects during treatment.

##### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Teponi

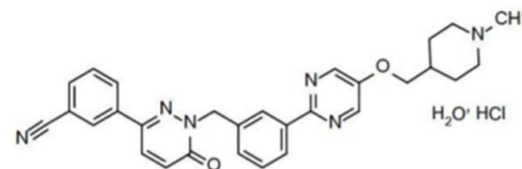
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and the bottle label after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- Do not use this medicine if you notice that tablet look damaged.
- 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 to protect the environment.

#### 6. Contents of the pack and other information

#### What Teponi contains

The active substance is : tepotinib , Teponi is a kinase inhibitor. Teponi (tepotinib) tablets for oral use are formulated with tepotinib hydrochloride hydrate. The chemical name for tepotinib hydrochloride hydrate is 3-([3-({3-[(1-methylpiperidin-4-yl)methoxy]pyrimidin-2-yl}phenyl)methyl]-6-oxo-1,6-dihydropyridazin-3-yl) benzonitrile hydrochloride hydrate. The molecular formula is  $C_{23}H_{28}N_6O_2 \cdot HCl \cdot H_2O$  and the molecular weight is 547.05 g/mol for tepotinib hydrochloride hydrate and 492.58 g/mol for tepotinib (free base). The chemical structure is shown below:



Teponi is supplied as film-coated tablets containing 225 mg of tepotinib (equivalent to 250 mg tepotinib hydrochloride hydrate).

The other ingredients are:

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

##### What Teponi looks like and the contents of the bottle

Tablets: 225 mg, white-pink, oval, biconvex film-coated tablets

Each carton contains 1 child-resistant plastic bottle containing 30 tablets or 60tablets.

##### Marketing Authorisation Holder

Tongmeng(Lao) Pharmaceutical and Food Co., Ltd  
Rd13 South,31km,Ban Naphasuk,Saithany District  
Vientiane  
Lao PDR

##### Manufacturer

Tongmeng(Lao) Pharmaceutical and Food Co., Ltd  
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:



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