



# Information for the patient

## SotoraiB 120 mg film-coated tablets

### Sotorasib

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.

#### What is in this leaflet

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

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

SotoraiB contains the active substance sotorasib and belongs to a group of medicines known as antineoplastic agents (cancer medicines).

SotoraiB is used to treat adults with a type of lung cancer called non-small cell lung cancer (NSCLC) when it is advanced and has spread to other parts of the body.

SotoraiB is used when previous treatments were not effective in stopping the growth of the cancer, and when the cancer cells have a genetic change that allows them to produce an abnormal form of protein called KRAS G12C. Your doctor will test your cancer cells for this change beforehand to make sure that SotoraiB is right for you.

#### How does SotoraiB work?

The abnormal KRAS G12C protein, acts to help make cancer cells grow out of control. SotoraiB attaches to the protein and stops it from working, which may slow down or stop the growth of the cancer.

If you have any questions about how SotoraiB works or why this medicine has been prescribed for you, ask your doctor, pharmacist, or nurse.

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

##### Do not take SotoraiB

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

##### Warnings and precautions

Talk to your doctor, pharmacist, or nurse before taking SotoraiB.

Tell your doctor, pharmacist or nurse if you have a history of liver problems. Your doctor may carry out blood tests to check your liver function, and may decide to either reduce the dose of SotoraiB or stop your treatment.

Tell your doctor if you have ever had any other lung problems. Some lung problems may get worse during treatment with SotoraiB, as SotoraiB may cause inflammation of the lungs during treatment. Symptoms may be similar to those from lung cancer. Tell your doctor right away if you have any new or worsening symptoms including difficulty in breathing, shortness of breath, or cough with or without mucous, or fever.

#### Children and adolescents

SotoraiB has not been studied in children or adolescents. Treatment with SotoraiB is not recommended in persons under 18 years of age.

#### Other medicines and SotoraiB

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, vitamins and herbal supplements. This is because SotoraiB can affect the way some other medicines work, and some other medicines can affect the way SotoraiB works.

#### The following medicines may reduce how well SotoraiB works:

- Medicines used to reduce stomach acid and to treat stomach ulcers, indigestion and heartburn (see section 3) such as:
  - dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole sodium, or rabeprazole (medicines known as 'proton pump inhibitors')
  - ranitidine, famotidine, cimetidine (medicines known as 'H2 receptor antagonists')
- Rifampicin (used to treat tuberculosis)
- Medicines used to treat epilepsy called phenytoin, phenobarbital or carbamazepine (also used to treat nerve pain)
- St. John's wort (herbal medicine used to treat depression)
- Enzalutamide (used to treat prostate cancer)

#### SotoraiB may reduce how well the following medicines work:

- Medicines used to treat severe pain, such as alfentanil or fentanyl
- Medicines used in organ transplantation to prevent organ rejection, such as cyclosporine, sirolimus, everolimus, or tacrolimus
- Medicines used to reduce cholesterol levels, such as simvastatin, atorvastatin, or lovastatin
- Midazolam (used to treat acute seizures or as a sedative before or during surgery or medical procedures)
- Medicines used to treat heart rhythm problems, such as dronedarone or amiodarone
- Medicines known as anticoagulants that stop your blood clotting, such as rivaroxaban or apixaban

#### SotoraiB may increase the risk for side effects with the following medicines:

- Medicines used to treat certain cancers or inflammatory conditions, such as methotrexate, mitoxantrone, topotecan or lapatinib
- Medicines used to treat heart failure, such as digoxin

#### Contraception

If you take SotoraiB whilst using oral contraceptives, the oral contraceptives may be ineffective. In addition, you should use another reliable method of birth control such as a barrier method (e.g. condom) so you do not become pregnant while you are taking this medicine. Talk to your doctor about the right methods of contraception for you and your partner.

#### Pregnancy, breast-feeding and fertility

##### Pregnancy

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

You should not become pregnant while taking this medicine because the effects of SotoraiB in pregnant women are not known, it could harm the baby. If you are able to become pregnant, you must use highly effective contraception while on treatment and for at least 7 days after stopping treatment.

##### Breast-feeding

Do not breast-feed while taking this medicine and for 7 days after the last dose. This is because it is not known whether the ingredients in SotoraiB pass into breast milk and could therefore harm your baby.

##### Driving and using machines

SotoraiB has no marked influence on the ability to drive and use machines.

##### SotoraiB contains lactose

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

##### SotoraiB contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodiumfree'.

#### 3. How to take SotoraiB

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

Do not change your dose or stop taking Sotoroib unless your doctor or pharmacist tells you to. Your doctor or pharmacist may decrease the dose or stop your medicine depending on how well you tolerate it.

- The recommended dose is eight tablets (960 mg) once a day. Take your daily dose of Sotoroib by mouth once a day, at the same time each day.
- Sotoroib can be taken with or without food.
- Swallow the tablets whole. You can disperse the tablets in water but do not chew, crush, or split the tablets.
- If you cannot swallow Sotoroib tablets whole:
  - Place your daily dose of Sotoroib in half a glass (not less than 120 mL) of plain, room temperature drinking water, without crushing the tablets. Do not use any other liquids, including acidic beverages (e.g. fruit juices).
  - Swirl gently until the tablets are in small pieces (the tablets will not dissolve completely). The appearance of the mixture may range from pale to bright yellow.
  - Drink the mixture right away.
  - Rinse the glass with an additional half a glass of water and drink right away to make sure that you have taken the full dose of Sotoroib.
  - If you do not drink all of the mixture immediately, stir the mixture again before you finish drinking it. Drink all of the mixture within two hours of preparation.

If you need to take a medicine to reduce stomach acid, proton pump inhibitors and H2 receptor antagonists are not recommended (see section 2). You may use a local antacid and Sotoroib should be taken either 4 hours before or 10 hours after that medicine (see section 2).

#### **If you take more Sotoroib than you should**

Contact your doctor, pharmacist or nurse immediately if you take more tablets than recommended.

#### **If you vomit after taking Sotoroib**

If you vomit after taking a dose of Sotoroib, do not take an extra dose. Take your next dose at your regular scheduled time.

#### **If you forget to take Sotoroib**

If you forget to take a dose of Sotoroib at your regular scheduled time, and less than 6 hours have passed, take your dose as normal. If more than 6 hours have passed from your regular scheduled time, do not take the dose. Take your next dose at your regular scheduled time the next day.

### **4. Possible side effects**

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

Very common and serious possible side effects of Sotoroib are increased blood levels of certain liver enzymes (AST/ALT), which are a sign of liver problems. Your doctor may do blood tests to check how well your liver is working and may decide to either reduce the dose of Sotoroib or stop your treatment (see section 2).

Other possible side effects of Sotoroib may include:

#### **Very common (may affect more than 1 in 10 people)**

- Diarrhoea
- Feeling sick (nausea)
- Feeling tired
- Vomiting
- Constipation
- Stomach pain
- Fever
- Joint pain
- Back pain
- Shortness of breath
- Cough
- Low red blood cell count (anaemia) which may cause tiredness and fatigue
- Headache

#### **Common (may affect up to 1 in 10 people)**

- High levels of some enzymes including blood enzymes seen in tests (increased alkaline phosphatase, bilirubin and gamma-glutamyltransferase)
- Liver injury

#### **Uncommon (may affect up to 1 in 100 people)**

- Inflammation of the lungs called “interstitial lung disease”

#### **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 Sotoroib**

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 blister after EXP. The expiry date refers to the last day of that month.

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

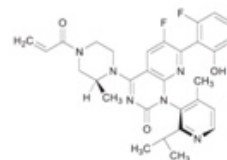
This medicine does not require any special storage conditions.

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 Sotoroib contains**

-The active substance is sotorasib. Each film-coated tablet contains 120 mg of sotorasib. Sotorasib is an inhibitor of the RAS GTPase family. The molecular formula is C<sub>30</sub>H<sub>30</sub>F<sub>2</sub>N<sub>6</sub>O<sub>3</sub>, and the molecular weight is 560.6 g/mol. The chemical name of sotorasib is 6-fluoro-7-(2-(2-fluoro-6-hydroxyphenyl)-(1M)-1-[4-methyl-2-(propan-2-yl)pyridin-3-yl]-4-[(2S)-2-methyl-4-(prop-2-enoyl)piperazin-1-yl]pyrido[2,3-d]pyrimidin-2(1H)-one. The chemical structure of sotorasib is shown below:



-The other ingredients are:

- Cellulose, microcrystalline
- Lactose monohydrate
- Croscarmellose sodium
- Magnesium stearate
- The tablets are coated with:
  - Polyvinyl alcohol , titanium dioxide, macrogol , talc , and iron oxide yellow

See Sotoroib contains lactose and Sotoroib contains sodium in section 2.

#### **What Sotoroib looks like and contents of the pack**

Sotoroib is supplied as a yellow, oblong-shaped, film-coated tablet, with “TLPH” on one side .

- Sotoroib is provided in bottles containing 60 or 120 film-coated tablets .

Not all pack sizes may be marketed Marketing Authorisation Holder and Manufacturer

#### **Manufacturer**

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



TLPH