



TLPH

## Information for the patient

### Osiem 40mg/80mg film-coated tablets

osimertinib

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 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

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

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

Osiem is an epidermal growth factor receptor (EGFR) inhibitor, for the potential oral treatment of mutant-EGFR expressing solid tumors, including non-small cell lung cancer (NSCLC).

Osiem is an oral, irreversible and selective inhibitor of both EGFR sensitizing and T790M resistance mutations with selectivity over the wild type form of the receptor. Following observations of significant tumor inhibition of this mono-anilino-pyrimidine compound in animal models, early efficacy has been observed when administered clinically to patients with T790M positive EGFR-TKI resistant NSCLC, accompanied by an encouraging safety profile.

Osiem is used on its own to treat adult patients with a specific type of cancer of the lung (non-small cell lung cancer) that is identified by a change (mutation) in the gene for EGFR/T790M.

Osiem can be prescribed to you as your first treatment or if prior chemotherapy treatment has been insufficient.

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

##### Do not take Osiem

- if you are allergic to Osiem or any of the other ingredients of this medicine (listed in section 6)
- if you are taking a herbal medicine called St. John's Wort, used for depression. If you are not sure about this, talk to your doctor, pharmacist or nurse before taking this medicine.

##### Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine:

- if you are female, have a low body weight of less than 50 kg or have kidney problems. If any of these apply to you, your doctor may monitor you more closely as the side effects may be more pronounced.

Treatment with this medicine is not recommended if you have a severe kidney disease.

- if you have a history of lung inflammation (interstitial lung disease).
- if you have liver problems. Your doctor may do some liver tests. Treatment with this medicine is not

recommended if you have a severe liver disease.

- if you have a history of eye problems such as severe dry eyes, inflammation of the transparent layer short time.
- If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before taking this medicine.

#### Children and adolescents

Osiem should not be used in children and adolescents. This is because it has not been studied in these age groups.

#### Other medicines and Osiem

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

if taken before Osiem, the following medicines may increase the blood levels of Osiem and therefore the risk of side effects. They should therefore be taken as far apart in time as possible from Osiem. Ritonavir, ketoconazole (except in shampoo), itraconazole, erythromycin, nelfinavir, saquinavir – used to treat different kinds of infections. Verapamil, quinidine, amiodarone – used to treat heart conditions. Cyclosporine A, tacrolimus – medicines that affect your immune system.

The following medicines may reduce the effectiveness of Osiem:

- Carbamazepine, phenytoin, phenobarbital – used to treat seizures.
- St. John's wort (Hypericum perforatum), a herbal medicine to treat depression.
- Rifampicin, an antibiotic used to treat tuberculosis.

Tell your doctor before taking these medicines together with Osiem

#### Pregnancy, breast-feeding and fertility

Do not get pregnant while you are taking this medicine. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this medicine.

Osiem should not be used during pregnancy. There is no information about the safety of Osiem in pregnant women.

Women of childbearing age must use a highly effective method of birth control during and up to three months after receiving IMBRUTINIB, to avoid becoming pregnant while being treated with Osiem. If using hormonal contraceptives such as birth control pills or devices, a barrier method of contraception (e.g. condoms) must also be used.

Tell your doctor immediately if you become pregnant.  
Do not breast-feed while you are taking this medicine.

#### 3. How to take Osiem

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

##### How much to take

The recommended dose of Osiem is one tablet (40/80mg) once a day.  
Your doctor may adjust (increase or decrease) your dose depending on how well you tolerate this medicine.  
Taking this medicine  
Take the tablets orally (by mouth) with a glass of water.  
Take the tablets about the same time each day.  
Swallow the tablets whole. Do not open, break or chew them.

##### If you take more Osiem than you should

If you take more Osiem than you should, talk to a doctor or go to a hospital straight away.  
Take the tablets and this leaflet with you.

##### If you forget to take Osiem

If you miss a dose, it can be taken as soon as possible on the same day with a return to the normal schedule the following day.

Do not take a double dose to make up for a forgotten dose.

If you are not sure, talk to your doctor, pharmacist or nurse about when to take your next dose.

#### If you stop taking Osiem

Do not stop taking this medicine unless your doctor tells you.

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

#### 4. Possible side effects.

##### The most common adverse events were diarrhoea (30%), rash (24%) and nausea (17%)

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

Contact your doctor as soon as possible if you suffer from any of the serious side effects listed below. In some cases your doctor may need to interrupt treatment and reduce your dose or stop treatment:

- Diarrhoea (very common, may affect more than 1 in 10 people).

Diarrhoea lasting more than 2 days or more severe diarrhoea may lead to fluid loss, low blood Potassium (common) and worsening kidney function (common). Diarrhoea can be treated. At the first signs of diarrhoea drink plenty of fluids. Contact your doctor immediately and start appropriate antidiarrhoeal treatment as soon as possible. You should have antidiarrhoeal medicine available prior to taking Osiem

- Skin rash (very common).

It is important to treat the rash early. Tell your doctor if a rash starts. If treatment for rash is not working and the rash is getting more severe (for example, you have peeling or blistering of the skin) you should notify your doctor immediately, since your doctor may decide to stop your treatment with Osiem. Rash may occur or worsen in areas exposed to sun. Sun protection with protective clothing and sunscreen is recommended.

Inflammation of the lungs (uncommon, may affect up to 1 in 100 people) called "interstitial lung disease".

Tell your doctor immediately if you develop new or sudden worsening of shortness of breath, possibly with a cough or fever.

Eye irritation or inflammation

Eye irritation or inflammation may occur (conjunctivitis/keratoconjunctivitis occurs commonly and keratitis uncommonly). Tell your doctor if you have sudden or worsening of eye symptoms such as pain or redness or dry eye.

If you experience any of the symptoms above, contact your doctor as soon as possible.

The following other side effects have also been reported:

Very common side effects :

- Mouth sores and inflammation
- Nail infection
- Decreased appetite
- Bleeding from the nose

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

- Pain, redness, swelling or peeling of the skin of your hands and feet
- Increased levels of the liver enzymes in blood tests.
- Inflammation of the lining of the bladder with burning sensations during urination and frequent, urgent need to urinate (cystitis)
- Abnormal taste sensations (dysgeusia)
- Stomach pain, indigestion, heartburn
- Lip inflammation
- Decreased weight
- Runny nose
- Muscle spasms
- Fever

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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

#### 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. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Osiem

Store Osiem at room temperature between 68°F to 77°F (20°C to 25°C).

- Safely throw away medicine that is out of date or that you no longer need.
- Keep Osiem and all medicines out of the reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle label after EXP.

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

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 Osiem contains

The active substance is Meveretinib. Each film-coated tablet contains 40/80 mg of Meveretinib.

Tablet core:

- tablet content: Mannitol, L-HPC, Sodium stearyl fumarate, microcrystalline cellulose

Film-coating:

-Polyvinyl alcohol, titanium dioxide, macrogol 3350, talc, sunset yellow FCF aluminium lake (E110)

##### What Osiem looks like and contents of the pack

Osiem film-coated tablets are yellow, diamond-shaped tablets debossed with "TLPH" on one side

The tablets are provided in a plastic bottle with a child resistant polypropylene closure. Each bottle contains either 60 tablets. Each pack contains one bottle. They are available in aluminium perforated unit dose blisters in packs of 10 x 3 tablets.

##### 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

Rd13 South,31km,Ban Naphasuk,Saithany District

Vientiane

Lao PDR

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:



TLPH