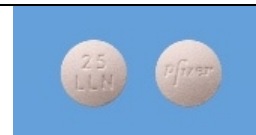


# Drug Information Sheet("Kusuri-no-Shiori")

Internal  
Revised: 06/2022

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

**Brand name:**LORBRENA Tablets 25mg**Active ingredient:**Lorlatinib**Dosage form:**very light red tablet, diameter: 8.0 mm, thickness: approximately 4.0 mm**Imprint or print on wrapping:**LORBRENA 25mg, ローブレナ 25mg, 25 LLN, pfizer**Effects of this medicine**

This medicine has an anti-tumor effect by suppressing the effect of anaplastic lymphoma kinase (ALK) fusion protein and by inhibiting the growth of tumor cells.

It is usually used to treat ALK fusion gene-positive unresectable advanced/recurrent non-small cell lung cancer.

**The following patients may need to be careful when using this medicine. Be sure to tell your doctor and pharmacist.**

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines or foods.  
If you have: interstitial lung disease or a history of it, a risk for or a history of QT interval prolongation, renal dysfunction or liver dysfunction.
- If you are pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

**Dosing schedule (How to take this medicine)**

- Your dosing schedule prescribed by your doctor is(( to be written by a healthcare professional))
- In general, for adults, take 4 tablets (100 mg of the active ingredient) at a time, once a day. The dosage may be decreased according to the condition. Strictly follow the instructions.
- If you miss a dose and notice it 4 or more hours before your next dose, take the missed dose and follow your regular dosing schedule. If it is less than 4 hours before your next dose, skip the missed dose and follow your regular dosing schedule. You should never take two doses at one time.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop taking this medicine unless your doctor instructs you to do so.

**Precautions while taking this medicine**

- Since interstitial lung disease may occur, chest CT is performed. As well, pulmonary function test may be performed if required.
- Since QT interval prolongation may occur, electrocardiogram and electrolyte tests and measurement of the pulse and the blood pressure are periodically performed before and while taking this medicine.
- Undergo the tests at specified dates and times.
- If you or your partner have a possibility of pregnancy, avoid pregnancy while you are taking this medicine and for a certain period after you discontinue this medicine.

**Possible adverse reactions to this medicine**

The most commonly reported adverse reactions include edema, peripheral neuropathy (decreased sensation, muscle weakness, etc.), weight gain, cognitive disorder, diarrhea and fatigue. If any of these symptoms occur, consult with your doctor or pharmacist.

**The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.**

- shortness of breath, dyspnea, fever [interstitial lung disease]
- chest pain, syncope, dizziness [QT interval prolongation]
- memory disturbance/forgetfulness/attentional disorder, speech difficulties, depression/anxiety [central nervous system disorder, mental disorder]
- severe pain in the upper abdomen or low back, fever, nausea [pancreatitis]
- general malaise, loss of appetite, yellowing of the skin and the white of eyes [liver dysfunction]

**The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.**

**Storage conditions and other information**

- Keep out of reach of children. Store at room temperature (1 to 30 degrees Celsius), away from direct sunlight and moisture.
- Discard the remainder. Do not store them. Please consult with your pharmacy or medical institution, since proper disposal of the unused medicines requires attention. Do not give the unused medicines to others.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.