

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

Internal

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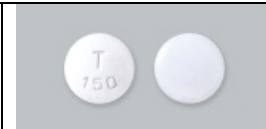
The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic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

Brand name:TARCEVA Tablets 150mg

Active ingredient:Erlotinib hydrochloride

Dosage form:white to yellowish white tablet (diameter: approx. 10.5 mm, thickness: approx. 5.4 mm)

Imprint or print on wrapping:T150 タルセバ 150mg



Effects of this medicine

This medicine inhibits the growth of non-small cell lung cancer by selectively suppressing the function of epidermal growth factor receptor (EGFR), a protein necessary for cancer cell growth.

It is usually used to treat unresectable, recurrent and progressive non-small cell lung cancer which has worsened after cancer chemotherapy or to treat unresectable, recurrent and progressive chemotherapy-naïve non-small cell lung cancer with EGFR mutation.

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 gastrointestinal ulcer or intestinal diverticulum or lung infection.
If you have ever had of those diseases mentioned above.
If you have liver disorder.
- 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 1 tablet (150 mg of erlotinib) at a time once a day, either over 1 hour before meal or over 2 hours after meal. The dosage may be decreased according to your symptoms. Strictly follow the instructions.
- Avoid taking the medicine from just 1 hour before meal to 2 hours after meal. Otherwise, you may have stronger adverse reactions.
- If you miss a dose, take the missed dose on an empty stomach. However If it is almost time for the next dose, skip the missed dose and continue 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. You may have severe diarrhea, rash, or elevation of ALT (GPT) /AST (GOT).
- Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- This medicine may cause serious adverse reactions. You should be informed of precautions until you fully understand them.
- The medicine may cause adverse reactions such as interstitial lung disease, rash, diarrhea, and corneal perforation/ulcer. If you have symptoms such as shortness of breath, respiratory distress, cough, fever, rash, diarrhea, and ocular pain, or if you feel that those symptoms have worsened, receive medical examination immediately.
- Patients with a possibility of pregnancy should avoid pregnancy appropriately while using this medicine and for 2 weeks after the completion of this medication.
- Refrain from taking grapefruit juice or any food containing Saint John's wort, or tobacco (smoking) because they affect this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include acneform rash, diarrhea, stomatitis, dry skin/skin crack, nail disorders such as periodontitis, loss of appetite, infections (skin/lung/upper respiratory tract infection), constipation, pruritus, anemia, nausea, vomiting, malaise, fever, fatigue, taste abnormality, weight loss and alopecia. 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.

- cough, shortness of breath, breathing difficulty [interstitial lung disease (interstitial pneumonia, pneumonitis, irradiation pneumonitis, organized pneumonia, pulmonary fibrosis, acute respiratory distress syndrome, pulmonary infiltration, alveolitis)]
- fever, generalized redness, skin and mucous erosion [severe skin disorder]
- repeated watery stool, lower abdominal pain, body dullness [severe diarrhea]
- nausea, vomiting, chills, fever, light headedness [gastrointestinal perforation, gastrointestinal ulcer, gastrointestinal bleeding]
- foggy vision, ocular pain, foreign body sensation in the eyes [corneal perforation, corneal ulcer]

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 the reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. If you do not know how to discard, consult your pharmacy or medical institution about how to discard them. Do not give this medicine to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.