

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

Internal

Revised: 10/2022

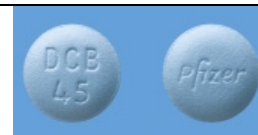
The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic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

Brand name:VIZIMPRO Tablets 45mg

Active ingredient:Dacomitinib hydrate

Dosage form:blue tablet, diameter: approx. 9.0 mm, thickness: approx. 4.5 mm

Imprint or print on wrapping:VIZIMPRO, ビジンプロ, 45mg, DCB 45, pfizer



Effects of this medicine

This medicine suppresses tumor growth by inhibiting active mutated epidermal growth factor receptor (EGFR) tyrosine kinase.

It is usually used to treat EGFR mutation positive inoperable or 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 its history 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 1 tablet (45 mg of dacomitinib) at a time, once a day. The dosage may be decreased according to the condition. Strictly follow the instructions.
- EGFR mutation test is performed before taking this medicine; this medicine is prescribed to patients positive for EGFR mutation.
- If you miss a 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

- Chest imaging test is periodically performed since interstitial lung disease may occur. In addition, lung function test is performed as needed. If symptoms such as shortness of breath, dyspnea, cough and fever occur while taking this medicine, discontinue this medicine and contact your doctor immediately.
- Liver function test is performed before and periodically while taking this medicine since liver dysfunction may occur.
- Female patients with a possibility of getting pregnant should properly avoid pregnancy while taking this medicine and for a certain period after discontinuation of this medicine.
- Discontinue breastfeeding while taking this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include diarrhea, paronychia, stomatitis (oral ulceration, aphthous ulcer, etc.), acneiform dermatitis and rash/maculopapular rash/erythematous eruption. 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, respiratory distress, fever [interstitial lung disease]
- muddy or watery stool, abdominal pain, dehydration [severe diarrhea]
- general redness, erosion of skin/mucosa, blister [severe dermatopathy]
- 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. If you do not know how to dispose of the unused medicines, seek advice of your pharmacy or medical institution. Do not give the unused medicines to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.