

VIZIMPRO® (Dacomitinib)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

What is VIZIMPRO?

VIZIMPRO is a prescription medicine used to treat non-small cell lung cancer (NSCLC) that has spread to other parts of the body (metastatic):

- As your first treatment, if your tumor has certain types of abnormal epidermal growth factor receptor (EGFR) gene(s).

Your healthcare provider will perform a test to make sure that VIZIMPRO is right for you.

It is not known if VIZIMPRO is safe and effective in children.

Before taking VIZIMPRO, tell your healthcare provider about all your medical conditions, including if you:

- have frequent diarrhea.
- have a history of lung or breathing problems other than lung cancer.
- are pregnant, or plan to become pregnant. VIZIMPRO can harm your unborn baby.

Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with VIZIMPRO.
- You should use effective birth control (contraception) during treatment and for at least 17 days after your last dose of VIZIMPRO. Talk to your healthcare provider about birth control methods that may be right for you during this time.
- Tell your healthcare provider right away if you become pregnant during your treatment with VIZIMPRO.
- are breastfeeding or plan to breastfeed. It is not known if VIZIMPRO passes into your breast milk. Do not breastfeed during treatment and for at least 17 days after your last dose of VIZIMPRO. Talk to your healthcare provider about the best way to feed your baby during this time.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. VIZIMPRO and other medicines or supplements may affect each other causing side effects.

How should I take VIZIMPRO?

- Take VIZIMPRO exactly as your healthcare provider tells you.
- Take your dose at approximately the same time each day.

- Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with VIZIMPRO if you have side effects.
- Take VIZIMPRO 1 time each day with or without food.
- If you take an antacid or H2 blocker medicine during treatment with VIZIMPRO, take your dose of VIZIMPRO **at least 6 hours before or 10 hours after** taking the antacid or H2 blocker medicine. Do not change your dose or stop taking VIZIMPRO unless your healthcare provider tells you.
- If you vomit or miss a dose of VIZIMPRO, do not take another dose or make up for the missed dose. Take your next dose at your regular time.

What should I avoid during treatment with VIZIMPRO?

Minimize exposure to sunlight. VIZIMPRO can cause skin reactions. See “**What are the possible side effects of VIZIMPRO?**”

What are the possible side effects of VIZIMPRO?

VIZIMPRO may cause serious side effects, including:

- **Lung or breathing problems.** VIZIMPRO may cause severe inflammation of the lung that may lead to death. Symptoms may be similar to those symptoms from lung cancer. Tell your healthcare provider right away if you have any new or worsening lung symptoms, including trouble breathing or shortness of breath, cough, or fever.
- **Diarrhea.** Diarrhea is common during treatment with VIZIMPRO, and can be severe and lead to death. Diarrhea can cause you to lose too much body fluid (dehydration). Your healthcare provider may tell you to start drinking more fluids or start taking your anti-diarrheal medicines. Tell your healthcare provider right away, if you have any loose stools or have stools more often than is normal for you.
- **Skin reactions.** Skin reactions are common with VIZIMPRO and can be severe. These skin reactions may include: dry skin, redness, rash, acne, itching, and peeling or blistering of your skin. Use moisturizers every day when taking VIZIMPRO. Use sunscreen and wear protective clothing that covers your skin, while exposed to sunlight, while you are taking VIZIMPRO. Your healthcare provider may prescribe other medicines to help skin reactions. Tell your healthcare provider right away about any worsening skin reactions.

The most common side effects of VIZIMPRO include:

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|------------------------|------------------------|
| • rash | • dry skin |
| • diarrhea | • decreased appetite |
| • mouth pain and sores | • decreased weight |
| • nail inflammation | • dry, red, itchy eyes |
| • common cold | • hair loss |
| | • itching |

Call your doctor for medical advice about side effects.

How should I store VIZIMPRO?

Please refer to the outer packaging for the recommended storage condition.

Keep VIZIMPRO and all medicines out of the reach of children.

General information about the safe and effective use of VIZIMPRO

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use VIZIMPRO for a condition for which it was not prescribed. Do not give VIZIMPRO to other people, even if they have the same symptoms you have. It may harm them.

You can ask your pharmacist or healthcare provider for more information about VIZIMPRO that is written for health professionals.

What are the ingredients in VIZIMPRO?

Active ingredient: dacomitinib

Inactive ingredients: lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, and magnesium stearate.

Film coating contains: Opadry II[®] Blue 85F30716 containing: Polyvinyl alcohol – partially hydrolyzed, Talc, Titanium dioxide, Macrogol/PEG 3350, and FD&C Blue #2/Indigo Carmine Aluminum Lake.

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