



WHAT TO EXPECT WITH VIZIMPRO® (DACOMITINIB)

A guide to side effects and working with your healthcare team

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

- VIZIMPRO is used as a first treatment if tumors have 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.

SELECTED SAFETY INFORMATION

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.

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VIZIMPRO®
DACOMITINIB
45mg, 30mg, 15mg tablets



WORKING WITH YOUR HEALTHCARE TEAM TO HELP MANAGE SIDE EFFECTS IS AN IMPORTANT PART OF YOUR TREATMENT JOURNEY

It's common to be concerned about side effects before starting a new treatment.

That's why it's important to learn everything you can, so you're prepared to work closely with your doctor or nurse as soon as a side effect occurs.

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This brochure describes serious as well as the most common side effects of VIZIMPRO® (dacomitinib). For some of the most common side effects, you will find information about signs and symptoms to look out for and management strategies that may be used by you and your care partner along with your healthcare team. Some of the management tips provided focus on supporting people with cancer and are not specific to VIZIMPRO; however, they may help manage specific side effects seen with VIZIMPRO.

Please talk with your healthcare team first before deciding if any of these tips are right for you.

At the end of this brochure, we've included a Treatment Journal—a place where you can record any symptoms or side effects you experience. It also can be used to write down any questions or thoughts you have during treatment that you want to share with your healthcare provider. Having this journal to refer to during your appointments may make discussions with your healthcare team easier and more productive.

Knowing what to expect when taking VIZIMPRO and having open communication about side effects with your healthcare team can be empowering and may help you feel more in control.

Information in this guide is not intended to replace advice from your healthcare provider. Contact your healthcare provider at the **first sign** of any side effects or if you have questions about VIZIMPRO.

SELECTED SAFETY INFORMATION

VIZIMPRO may cause serious side effects, including:

- **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.

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TABLE OF CONTENTS

Serious and most common side effects associated with VIZIMPRO® (dacomitinib)5

When side effects may occur.....6

General approaches to help manage side effects.....8

 Diarrhea 10

 Mouth sores 12

 Skin changes..... 14

 Nail disorders 18

Important Safety Information 20

Treatment Journal 22

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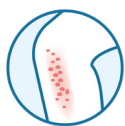
VIZIMPRO may cause serious side effects, including:



- **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:

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

These are not all of the possible side effects of VIZIMPRO. You can ask your pharmacist or healthcare provider for more information about VIZIMPRO that is written for health professionals.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

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Immediately contact your healthcare provider at the first sign of any side effects.

WHEN SIDE EFFECTS MAY OCCUR

The following pages of this guide will discuss some of the most common side effects experienced with VIZIMPRO® (dacomitinib) in more detail. People experience side effects differently—some people experience these side effects earlier, later, or not at all.

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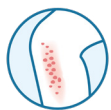
Some side effects typically occur earlier during treatment with VIZIMPRO, while others are more likely to occur later.



For people who experience diarrhea while taking VIZIMPRO, it generally first occurs around the **first week** of treatment, but might first occur much earlier or much later for some people.



For people who experience mouth sores while taking VIZIMPRO, these sores generally first occur around the **first week** of treatment, but might first occur much earlier or much later for some people.



For people who experience rash while taking VIZIMPRO, it generally first occurs around the **second week** of treatment, but might first occur much earlier or much later for some people.



For people who experience nail disorders while taking VIZIMPRO, these disorders generally first occur **several weeks** after starting treatment, but might first occur much earlier or much later for some people.



For people who experience dry skin while taking VIZIMPRO, it generally first occurs **several weeks** after starting treatment, but might first occur much earlier or much later for some people.

SELECTED SAFETY INFORMATION

VIZIMPRO may cause serious side effects, including:

- **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.

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GENERAL APPROACHES TO HELP MANAGE SIDE EFFECTS

If you have side effects, your healthcare provider may:



Prescribe or recommend products to help manage the side effect



Temporarily stop your treatment



Change your dose



Permanently stop your treatment

Remember, take VIZIMPRO® (dacomitinib) exactly as your healthcare provider tells you to take it. Do not stop taking VIZIMPRO unless they tell you to stop.

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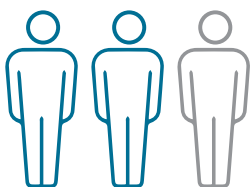
Managing side effects by temporarily stopping treatment

Your healthcare provider may temporarily stop your treatment with VIZIMPRO. This is a common way to help address side effects. In a clinical study, about half of people (57%; 129 out of 227 people) had to temporarily stop taking VIZIMPRO due to side effects. The most frequent side effects that led to this temporary stop were rash (23%), nail disorders (13%), and diarrhea (10%).

18% of people (41 out of 227 people) permanently stopped treatment with VIZIMPRO due to side effects, the most common of which were rash (2.6%), lung or breathing problems (1.8%), mouth sores (0.9%), and diarrhea (0.9%).

Managing side effects through dose changes

Another way your healthcare provider may help address some of the side effects is by changing your dose of VIZIMPRO.



In a clinical study of VIZIMPRO, 2 out of 3 people (66%; 150 out of 227 people) had their dose lowered. The most common side effects leading to dose reductions were rash (29%), nail disorders (14%), and diarrhea (8%).

Remember, your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with VIZIMPRO if you have side effects.

SELECTED SAFETY INFORMATION

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.

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DIARRHEA

Diarrhea is common during treatment with VIZIMPRO® (dacomitinib), and can be severe and lead to death.

- If not treated properly, 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 an anti-diarrheal medicine



Diarrhea is defined as 3 or more loose or watery stools/bowel movements in 1 day. If you have these signs, call your healthcare provider right away. It is important to manage diarrhea as soon as it begins.

Dehydration is serious. Let your healthcare provider know if you have any of these signs of dehydration: dry mouth, dizziness, fever, or little or no urine.

In a clinical study, 87% of people (198 out of 227 people) experienced diarrhea with VIZIMPRO. 8% of cases were severe.

Signs and symptoms

Loose stools

Stools more often than usual

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Talk to your healthcare provider

- When you first experience diarrhea

Your healthcare provider may:

- Recommend an over-the-counter anti-diarrheal medicine, such as loperamide
- Give you a prescription for other products to help manage your diarrhea
- Temporarily stop your VIZIMPRO treatment and adjust your dose
- Choose to stop your VIZIMPRO treatment permanently

You may want to consider the following general tips:

- Eating more foods that are high in sodium and potassium (including bananas, oranges, boiled or mashed potatoes, and peach or apricot nectar), because you lose these important nutrients when you have diarrhea
- Drinking 8 to 10 large glasses of clear liquids each day to replace fluids lost. Avoid alcoholic drinks and soft drinks as they can make diarrhea worse
- Eating 5-6 small meals and snacks throughout the day instead of 3 large meals
- Avoiding spicy and fatty foods, caffeine, and raw fruit as they can make diarrhea worse

Remember, these are tips that are not intended to replace the advice of your healthcare team. Before you consider any changes to your diet, be sure to talk to your healthcare team.

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MOUTH SORES

Mouth sores, also known as stomatitis, are a possible side effect of VIZIMPRO® (dacomitinib). Stomatitis is an inflammation of the lining of the mouth. It may be accompanied by ulcers (sores or lesions).

In a clinical study, 45% of people (102 out of 227 people) experienced stomatitis with VIZIMPRO. 4.4% of cases were severe.

Signs and symptoms

Red, sore, or bleeding gums

Sores in the mouth, on the lips, or on the tongue

Pain or discomfort in and around the mouth

Difficulty eating or drinking

Talk to your healthcare provider

- Immediately if you experience discomfort or visible changes in and around the mouth
- If you have been treating your sore mouth according to your healthcare provider's instructions but it does not improve

Your healthcare provider may:

- Recommend a topical pain reliever or soothing mouth rinses, lozenges, or gels
- Temporarily stop your VIZIMPRO treatment and adjust your dose
- Choose to stop your VIZIMPRO treatment permanently

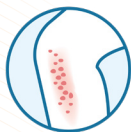
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You may want to consider the following general tips:

- Practicing good mouth care, such as using a soft toothbrush to gently brush the teeth and regularly rinsing with warm water and salt. Avoid chlorhexidine- or alcohol-containing oral products
- Eating foods cold or at room temperature as you may have increased sensitivity to hot or very cold foods. Try to eat soft, soothing, and moist food, such as mashed potatoes or scrambled eggs. These foods are easier to swallow when your mouth is sore
- Avoiding acidic or irritating juices and foods, spicy or salty foods, and rough or coarse foods, like raw vegetables, granola, or crackers
- Sipping water throughout the day, using a straw. A straw can help push drinks beyond the painful parts of your mouth

Remember, these are tips that are not intended to replace the advice of your healthcare team. Before you consider any changes to your diet, be sure to talk to your healthcare team.

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SKIN CHANGES

Skin reactions are common with VIZIMPRO® (dacomitinib) and can be severe. These skin reactions may include dry skin, redness, rash, acne, itching, and peeling or blistering of the skin. Get medical attention right away if you develop severe skin reactions, such as peeling or blistering of the 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.

Rash

In a clinical study, 69% of people (157 out of 227 people) experienced rash with VIZIMPRO. 23% of cases were severe.

Signs and symptoms

Itching, burning, or pain of skin

Redness, swelling, crusty and very dry skin

Bumps with a “pus-filled” appearance



Rash may look like acne (pimples), but it is not acne. Acne medicine may irritate the skin, which can make the rash worse.

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Dry skin

In a clinical study, 30% of patients (68 out of 227 patients) experienced dry skin with VIZIMPRO. 1.8% of cases were severe.

Signs and symptoms

Flaky, cracked, dry skin

Talk to your healthcare provider

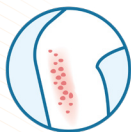
- Immediately to report any new or worsening rash or dry skin; early treatment of these conditions may prevent them from worsening

Your healthcare provider may:

- Give you a prescription for an antibiotic, either as a topical treatment or a tablet, or topical steroid
- Recommend an over-the-counter moisturizing cream
- Suggest mild soaps
- Temporarily stop your VIZIMPRO treatment and adjust your dose
- Choose to stop your VIZIMPRO treatment permanently

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SKIN CHANGES (cont)

You may want to consider the following general tips:

- Using a fragrance- and alcohol-free moisturizer on the face and body twice a day during treatment
- Avoiding long hot showers or baths, as this can further dry out the skin; wear gloves if you are doing the washing up or other tasks involving hot water and detergent
- Skin changes may be worse in sun-exposed areas—try to wear protective clothing outside and apply SPF 30 or above every two hours when outdoors and avoid being out in the sun for long periods
- Cleaning your skin gently with mild soap products

Remember, these are tips that are not intended to replace the advice of your healthcare team.

Below are some examples of products that may help you care for your skin. Ask your healthcare provider or pharmacist before use.

Mild soaps

Cetaphil® Gentle Skin Cleanser

Neutrogena® Ultra Gentle Hydrating Cleanser

Other mild soaps

Moisturizers

Cetaphil® Moisturizing Cream

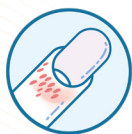
Other mild moisturizers

For itchy skin

Antihistamine drugs

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NAIL DISORDERS

A potential side effect of VIZIMPRO® (dacomitinib) is nail inflammation, also called paronychia. It involves inflammation surrounding the nails that may be accompanied by infection.

In a clinical study, 64% of people (145 out of 227 people) experienced nail disorders with VIZIMPRO. 8% of cases were severe.

Signs and symptoms

Red, swollen skin around your fingernails or toenails

In more severe cases, pus may collect around the nail. The cuticle and skin around it may separate from the nail

Talk to your healthcare provider

- If you feel discomfort or if inflammation is affecting your daily activities
- If you have been treating it according to your healthcare provider's instructions but it does not get better

Your healthcare provider may:

- Recommend creams to apply to the affected areas
- Prescribe an antibiotic to treat infection
- Temporarily stop your VIZIMPRO treatment and adjust your dose
- Choose to stop your VIZIMPRO treatment permanently

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You may want to consider the following general tips:

- Keeping affected areas dry
- Avoiding nail trauma, overly aggressive manicures/pedicures, biting the nails, and contact with irritating substances
- Wearing comfortable shoes and wearing gloves while performing household chores, such as gardening or dishwashing
- Taking extra precautions to make sure nails are dry and clean if exposed to moist environments, such as bartending, dishwashing, and swimming

Remember, these are tips that are not intended to replace the advice of your healthcare team.

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IMPORTANT SAFETY INFORMATION

VIZIMPRO® (dacomitinib)
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.

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.

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- 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.

What should I avoid during treatment with VIZIMPRO?

Minimize exposure to sunlight. VIZIMPRO can cause skin reactions.

The most common side effects of VIZIMPRO include:

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

These are not all of the possible side effects of VIZIMPRO. You can ask your pharmacist or healthcare provider for more information about VIZIMPRO that is written for health professionals.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

INDICATION

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

- VIZIMPRO is used as a first treatment if tumors have 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.

Click for the [Full Prescribing Information](#) and [Patient Information](#) or visit VIZIMPRO.com.



TREATMENT JOURNAL

Use this journal to keep track of any side effects you experience, your daily dose of VIZIMPRO® (dacomitinib), and any other thoughts or concerns. Then, bring it to your next doctor appointment and share the information with your healthcare provider.

You can also share what you are experiencing with your care partner and loved ones. Remember, side effects can be important signals that let your healthcare team know what's happening in your body.

NEXT APPOINTMENT: _____

Date:

Daily dose:

How do you feel?

Side effects:

Notes:

Date:

Daily dose:

How do you feel?

Side effects:

Notes:

Date:

Daily dose:

How do you feel?

Side effects:

Notes:

NEXT APPOINTMENT: _____

Date:

Daily dose:

How do you feel?

Side effects:

Notes:

Date:

Daily dose:

How do you feel?

Side effects:

Notes:

Date:

Daily dose:

How do you feel?

Side effects:

Notes:

NEXT APPOINTMENT: _____

Date:

Daily dose:

How do you feel?

Side effects:

Notes:

Date:

Daily dose:

How do you feel?

Side effects:

Notes:

Date:

Daily dose:

How do you feel?

Side effects:

Notes:

NEXT APPOINTMENT: _____

Date:

Daily dose:

How do you feel?

Side effects:

Notes:

Date:

Daily dose:

How do you feel?

Side effects:

Notes:

Date:

Daily dose:

How do you feel?

Side effects:

Notes:

NEXT APPOINTMENT: _____

Date:

Daily dose:

How do you feel?

Side effects:

Notes:

Date:

Daily dose:

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Notes:

Date:

Daily dose:

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Side effects:

Notes:



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VIZIMPRO may cause side effects which can be serious. **Please see Important Safety Information on pages 20-21.**

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Visit [VIZIMPRO.com](https://www.vizimpro.com) to find additional resources and support