

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

VIZIMPRO
Dacomitinib

Read this carefully before you start taking **VIZIMPRO** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **VIZIMPRO**.

Serious Warnings and Precautions

Take VIZIMPRO under the care of a doctor who knows how to use anti-cancer drugs.

VIZIMPRO has caused the following serious and/or life-threatening side effects

- diarrhea that may lead to death
- skin conditions including peeling or blistering of the skin
- lung problems that may lead to death

For further information and symptoms see :

- o the “Other warnings you should know about” section
- o the “Serious side effects and what to do about them” table

What is VIZIMPRO used for?

VIZIMPRO is a prescription medicine used in adults to treat a type of lung cancer called non-small cell lung cancer (NSCLC). VIZIMPRO is typically used as your first treatment when your cancer:

- cannot be removed with surgery or has spread to other parts of the body.
- has certain changes in the genes that produce a protein on the surface of the cells called epidermal growth factor receptor (EGFR).

Your doctor will test your lung cancer for the EGFR gene to see whether VIZIMPRO is right for you.

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

How does VIZIMPRO work?

Dacomitinib, the active substance in VIZIMPRO, belongs to a group of medicines called protein-tyrosine-kinase inhibitor. This means that it blocks the activity of a group of proteins called the HER family (including EGFR [epidermal growth factor receptor or HER1], HER2 [HER2], and HER4). These proteins are involved in the growth and spread of cancer cells, and can be affected by changes (mutations) in the genes that produce them. By blocking the activity of these proteins VIZIMPRO can inhibit growth and spread of cancer cells.

What are the ingredients in VIZIMPRO?

Medicinal ingredients: Dacomitinib (as dacomitinib monohydrate)

Non-medicinal ingredients: Lactose monohydrate, magnesium stearate, microcrystalline cellulose, and sodium starch glycolate.

Film coating contains: Opadry II® Blue 85F30716 containing: FD&C Blue #2/Indigo Carmine Aluminum Lake; Macrogol/PEG 3350; polyvinyl alcohol – partially hydrolyzed; talc; titanium dioxide.

VIZIMPRO comes in the following dosage forms:

Film-coated tablets 15 mg, 30 mg, 45 mg

Do not use VIZIMPRO if:

- You are allergic to dacomitinib or any of the other ingredients of VIZIMPRO

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take VIZIMPRO. Talk about any health conditions or problems you may have, including if you:

- have frequent diarrhea.
- have a history of lung or breathing problems other than lung cancer.
- have kidney problems.
- have a history of severe dry eye or any other eye problems.

For female patients who are able to become pregnant:

- Do not take VIZIMPRO if you are pregnant, or plan to become pregnant. VIZIMPRO can harm your unborn baby.
 - Use effective birth control during treatment and for at least 2 months after stopping VIZIMPRO. Talk to your healthcare provider about birth control methods that may be right for you during this time.
 - If you become pregnant or think you are pregnant, tell your healthcare provider right away.
- Do not take VIZIMPRO if you are breastfeeding or plan to breastfeed.
 - It is not known if VIZIMPRO passes into your breast milk. Do not breastfeed for at least 2 months after stopping VIZIMPRO.
 - Talk to your healthcare provider about the best way to feed your baby during this time.

For male patients with female partners who are able to become pregnant:

- VIZIMPRO can harm your unborn baby if your partner is pregnant or becomes pregnant while you are taking VIZIMPRO. Use effective birth control during treatment and for at least 2 months after stopping VIZIMPRO. Talk to your healthcare provider about birth control methods that may be right for you during this time. If your partner becomes pregnant or thinks she may be pregnant, tell your healthcare provider right away.

Other warnings you should know about:

- **Lung or breathing problems.** VIZIMPRO may cause severe inflammation of your lungs that may lead to death. Symptoms may be similar to those symptoms from lung cancer. Tell your doctor right away if you have any new or worsening lung problems, or any combination of the following symptoms: trouble breathing or shortness of breath, cough, or fever.
- **Diarrhea.** Diarrhea is very common in patients who are taking VIZIMPRO. Make sure

that you are drinking plenty of fluids while taking VIZIMPRO. Severe diarrhea can cause loss of too much body fluid (dehydration) and may even lead to death or cause kidney damage. It is important that if you have diarrhea, you contact your physician right away, you start taking your anti-diarrhea medicines (like loperamide), and you drink extra water or other rehydration formulas. Take this medicine exactly as your doctor tells you to. Get additional medical attention right away if your diarrhea does not go away or becomes severe.

- **Skin Conditions.** VIZIMPRO can cause dry skin, redness, rash, acne, peeling skin, and possible blistering of the skin including palms and soles. Start using skin moisturizers as soon as you start VIZIMPRO. It is important to get treatment for skin conditions as soon as you notice them. Take medicines to help skin conditions exactly as your doctor tells you to. Get medical attention right away if you develop severe skin reactions such as peeling or blistering of the skin, or blisters in your mouth. VIZIMPRO can make your skin sensitive to the sun. Use sunscreen and wear protective clothing that cover your skin while you are taking VIZIMPRO while exposed to sunlight.
- **Eyes Problems (keratitis):** VIZIMPRO can cause keratitis, swelling and inflammation of the cornea (the outer layer of the eye). Seek medical advice right away if you have any symptoms of keratitis such as: eye redness, eye pain, excess tearing, blurred vision or other vision changes, increased sensitivity to light, a feeling that a foreign object is trapped in your eye, and/or difficulty opening your eyelid because of pain or irritation.
- **Nails Problems (paronychia):** VIZIMPRO can cause paronychia (an infection of the skin that surrounds a toenail or fingernail). Tell your healthcare provider right away if you have any of the following symptoms in the skin around a nail: pain, redness, warmth and swelling, and/or unusual color. To prevent paronychia:
 - keep your hands and feet clean and dry
 - be gentle when you manicure your nails and avoid injury to your nails or finger tips
 - avoid chemicals that can be harmful, such as soaps, detergents and nail products

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines. VIZIMPRO and other medicines or supplements may affect each other causing side effects.

Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

The following may interact with VIZIMPRO:

Avoid the following medications during your treatment with VIZIMPRO:

- pimozone and thioridazine, drugs used to manage psychosis
- procainamide, a drug used to treat abnormal heart rhythms
- proton-pump inhibitors (long acting acid reducers that keep the stomach from making too much acid) such as dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole and rabeprazole.

- You can take a short-acting acid reducers (medications for stomach problems such as indigestion or heartburn), such as an antacid or an H2 blocker medicine. If you take H2 blocker medicine, take your dose of VIZIMPRO at least 2 hours before or 10 hours after taking the H2 blocker medicine.

How to take VIZIMPRO:

- Take VIZIMPRO exactly as your healthcare provider tells you.
- Take your dose at approximately the same time each day and with or without food.
- Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with VIZIMPRO if you have side effects.
- Swallow VIZIMPRO tablets whole. Do not chew or crush VIZIMPRO tablets before swallowing them.
- Do not take any VIZIMPRO tablets that are broken, cracked, or that look damaged.
- Do not change your dose or stop taking VIZIMPRO unless your healthcare provider tells you.

Usual dose:

Take VIZIMPRO 1 time each day with or without food, at approximately the same time each day.

Overdose:

If you take too much VIZIMPRO, call your healthcare provider right away or go to the nearest hospital emergency room.

If you think you have taken too much VIZIMPRO, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of VIZIMPRO or vomit after taking a dose of VIZIMPRO, do not take another dose on that day. Take your next dose at your regular time.

What are possible side effects from using VIZIMPRO?

These are not all the possible side effects you may feel when taking VIZIMPRO. If you experience any side effects not listed here, contact your healthcare professional.

Common side effects of VIZIMPRO include:

- diarrhea
- rash, itching, acne-like skin reactions, redness, swelling, and pain on the palms of the hands and/or the soles of the feet (Palmar-plantar erythrodysesthesia syndrome)
- dry skin or peeling skin
- sores and inflammation of mouth and lips
- nail changes and infections around the nail
- common cold, shortness of breath, cough
- loss of appetite, weight loss, changes in taste, dehydration
- fatigue, weakness
- dry, red, itchy eyes
- hair loss, increased hair growth
- nausea, vomiting, constipation
- muscle and limb pain

- difficulty sleeping
- lung inflammation

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON Diarrhea		√	
VERY COMMON Skin conditions: including peeling or blistering of the skin, or blisters in your mouth		√	
VERY COMMON Nails problems (paronychia): pain, redness, warmth, swelling in the skin around a nail		√	
COMMON Lung or breathing problems: including trouble breathing or shortness of breath, cough, or fever		√	
COMMON Eyes Problems (keratitis): eye redness, eye pain, excess tearing, blurred vision, decreased vision, increased sensitivity to light, a feeling that a foreign object is trapped in your eye, and/or difficulty opening your eyelid because of pain or irritation		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 15°C and 30°C in the original package to protect from moisture.

Keep out of reach and sight of children.

If you want more information about VIZIMPRO:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website <http://www.Pfizer.ca> or by calling 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC

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