

VIZIMPRO[®] FILM COATED TABLET

Dacomitinib (15mg, 30mg, 45mg)

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What VIZIMPRO is used for

VIZIMPRO contains the active substance dacomitinib, which is an oral kinase inhibitor. 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 can be used as your first treatment if your tumour has certain types of abnormal epidermal growth factor receptor (EGFR) gene(s).

Your doctor 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.

How VIZIMPRO works

VIZIMPRO inhibits the activity of epidermal growth factor receptor (EGFR) which is involved in development of cancer.

Before you use VIZIMPRO

- When you must not use it

If you are allergic to any of the ingredients present in VIZIMPRO.

Pregnancy and lactation

Do not take VIZIMPRO if you are pregnant, trying to get pregnant or think you may be pregnant. Your doctor may do a pregnancy test before you start treatment with VIZIMPRO and may also suggest you to use effective birth control

(contraception) during treatment and for at least 17 days after your last dose of VIZIMPRO. Talk to your doctor about birth control methods that may be right for you during this time.

You should not become pregnant during treatment with VIZIMPRO because this medicine could harm the baby. If you become pregnant while taking this medicine, you should immediately talk to your doctor.

It is not known if VIZIMPRO passes into your breast milk. Do not breast-feed while taking this medicine because it may potentially cause serious adverse reactions in your baby. Your doctor may advise you not to breastfeed during the treatment with VIZIMPRO and for at least 17 days after the last dose.

- Before you start use it

Talk to your doctor, pharmacist or nurse before taking VIZIMPRO:

- If you had any other lung problems. Some lung problems may get worse during treatment with VIZIMPRO, as VIZIMPRO may cause inflammation of the lungs during treatment. Symptoms may be similar to those from lung cancer. Tell your doctor right away if you have any new or worsening symptoms including difficulty in breathing, shortness of breath, or cough with or without phlegm (mucous), or fever.
- If you have frequent diarrhea.
- If you are pregnant, or plan to become pregnant.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Some medicines may reduce how well VIZIMPRO works, while some medications may become harmful when being taken with VIZIMPRO:

- Proton pump inhibitors for reducing stomach acid, such as rabeprazole may reduce the amount of VIZIMPRO in your blood and hence reduces the effectiveness of VIZIMPRO. Instead, you are advised to use locally-acting antacids (for eg. Maalox) or H₂-receptor antagonist (for eg. ranitidine).
- CYP2D6 substrate like dextromethorphan (used as a cough suppressant) may increase in concentration when taken with VIZIMPRO which may increase your risk of toxicity.

How to use VIZIMPRO

- How much to use

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- The recommended dose is 45 mg once daily by mouth.
- Take the tablet at about the same time each day.
- Take VIZIMPRO 1 time each day with or without meals.

Your doctor may change your dose, temporarily stop, or permanently stop treatment with VIZIMPRO if you have side effects.

Your doctor will modify the dose if you have:

- Inflammation of lungs
- Diarrhea
- Serious skin diseases

If you take an antacid or H₂ blocker medicine during treatment with VIZIMPRO, you are advised to take VIZIMPRO at least 6 hours before or 10 hours after taking the antacid.

- When to use it

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

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- How long to use it

Continue taking VIZIMPRO for as long as your doctor recommends.

- If you forget to use it

If you forget to take VIZIMPRO, take a dose as soon as you remember, then continue to take your medicine at the usual times. If you vomit or forget a dose, do not take a double dose to make up for the missed dose. Take your next dose at your regular time.

- If you use too much (overdose)

You should not take more medicine than your doctor tells you to.

If you are taking VIZIMPRO at doses greater than 45 mg once daily, you may experience gastrointestinal, skin and general problems such as tiredness, discomfort, and weight loss.

If you take more medicine than you have been told to take, you should take general supportive measures and contact your doctor immediately.

While you are using it

- Things you must do

Tell your doctor immediately while taking this medicine:

- if you develop diarrhoea.
- if you develop skin rash.
- If you develop lung symptoms such as shortness of breath, cough and fever.

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking VIZIMPRO.

Tell your doctor immediately if you become pregnant while taking this medication or intend to get pregnant.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give VIZIMPRO to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Tiredness and eye irritation can occur in patients taking Vizimpro. If you feel tired or your eyes are irritated, you should use caution when driving or using machines.

Side effects

Like all medicines, VIZIMPRO can cause side effects, although not everybody gets them.

Contact your doctor immediately if you notice any of the following side effects.

- Lung or breathing problems
- Diarrhea
- Adverse skin reactions

Tell your doctor as soon as possible if you notice any of the other following side effects:

- Mouth pain and sores
- Nausea
- Constipation
- Mouth ulcer
- Rash, nail inflammation, dry skin, hair loss, itching, redness, swelling, and pain on the palms and/or the soles
- Decreased weight and appetite
- Cough, nose and sinus disorder, difficulty in breathing, common cold, and chest pain
- Dry, red, or itchy eyes
- Pain in hand and foot and body pain.
- Tiredness or lack of energy
- Difficulty falling asleep
- Abnormal liver and blood tests
- Alteration in taste
- Peeling skin, and cracked skin
- Inflammation of eyes
- Abnormal amount of body hair growth
- Dehydration and vomiting

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of VIZIMPRO

- Storage

Keep out of the reach and sight of children.

Store below 30 °C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

VIZIMPRO tablets are blue film-coated, immediate release, round biconvex tablet. The tablets are debossed with “Pfizer” on one side and “DCB15” or “DCB30” or “DCB45” on the other side. The tablets are provided in blisters packs containing 3 blister strips with 10 tablets each.

- Ingredients

- Active ingredient(s)
The active substance is dacomitinib (as dacomitinib monohydrate).

- Inactive ingredients

Tablet core: lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, magnesium stearate.

Film coating: Opadry II Blue 85F30716 containing polyvinyl alcohol – partially hydrolysed (E1203), talc (E553b), titanium dioxide (E171), macrogol (E1521), Indigo carmine aluminium lake (E132).

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- *MAL number(s)*:

VIZIMPRO 15 MG FILM-COATED
TABLETS: MAL20076010AZ
VIZIMPRO 30 MG FILM-COATED
TABLETS: MAL20076011AZ
VIZIMPRO 45 MG FILM-COATED
TABLETS: MAL20076012AZ

Manufacturer

Pfizer Manufacturing Deutschland GmbH
Mooswaldallee 1,
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Under the authority of
Pfizer Inc., New York, N.Y., U.S.A.

Product Registration Holder

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