

Package leaflet: Information for the patient

Vizimpro 15 mg film-coated tablets
Vizimpro 30 mg film-coated tablets
Vizimpro 45 mg film-coated tablets
dacomitinib

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Vizimpro is and what it is used for
2. What you need to know before you take Vizimpro
3. How to take Vizimpro
4. Possible side effects
5. How to store Vizimpro
6. Contents of the pack and other information

1. What Vizimpro is and what it is used for

Vizimpro contains the active substance dacomitinib, which belongs to a group of medicines called protein tyrosine kinase inhibitors which are used to treat cancer.

Vizimpro is used to treat adults with a type of lung cancer called 'non-small cell lung cancer'. If a test has shown that your cancer has certain changes (mutations) in a gene called 'EGFR' (epidermal growth factor receptor) and has spread to your other lung or other organs, your cancer is likely to respond to treatment with Vizimpro.

Vizimpro can be used as your first treatment once your lung cancer has spread to your other lung or other organs.

2. What you need to know before you take Vizimpro

Do not take Vizimpro

- if you are allergic to dacomitinib or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

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

- if you ever 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 are being treated with any of the medicines listed in section *Other medicines and Vizimpro*.

Tell your doctor immediately while taking this medicine:

- if you develop diarrhoea. Immediate treatment of diarrhoea is important.
- if you develop skin rash. Early treatment of skin rash is important.
- if you have any symptoms of a liver problem which may include: yellowing of your skin or the white part of your eyes (jaundice), dark or brown (tea coloured) urine, light-coloured bowel movements (stools).

Children and adolescents

Vizimpro has not been studied in children or adolescents and it must not be given to patients under the age of 18 years.

Other medicines and Vizimpro

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, the effects of some medicines may increase when taken with Vizimpro. These include, among others:

- Procainamide, used to treat heart arrhythmias
- Pimozide and thioridazine, used to treat schizophrenia and psychosis

You should not take these medicines during your treatment with Vizimpro.

The following medicines may reduce how well Vizimpro works:

- Long-acting medicines for reducing stomach acid, such as proton pump inhibitors (for ulcers, indigestion and heartburn).

You should not take these medicines during your treatment with Vizimpro. As an alternative, you can take a short-acting medicine, 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.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

You should not become pregnant during treatment with Vizimpro because this medicine could harm the baby. If there is any possibility that you may become pregnant you must use effective contraception during treatment, and for at least 17 days afterwards. If you become pregnant while taking this medicine, you should immediately talk to your doctor.

Breast-feeding

Do not breast-feed while taking this medicine because it is not known if it can harm your baby.

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.

Vizimpro contains lactose and sodium

This medicine contains lactose (found in milk or dairy products). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially “sodium-free”.

3. How to take Vizimpro

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 taken by mouth each day.
- Take the tablet at about the same time each day.
- Swallow the tablet whole with a glass of water.
- You can take the tablet with or without meals.

Your doctor may decrease the dose of your medicine depending on how well you tolerate it.

If you take more Vizimpro than you should

If you have taken too much Vizimpro, see a doctor or go to a hospital immediately.

If you forget to take Vizimpro

If you miss a dose or vomit, take your next dose as scheduled. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Vizimpro

Do not stop taking Vizimpro unless your doctor tells you to. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Contact your doctor immediately if you notice any of the following side effects – you may need urgent medical treatment:

- Inflammation of the lungs (common, may affect up to 1 in 10 people)
Difficulty in breathing, shortness of breath, possibly with a cough or fever. This may mean that you have an inflammation of the lungs called interstitial lung disease and can be fatal.
- Diarrhoea (very common, may affect more than 1 in 10 people)
Diarrhoea may lead to fluid loss (common), low blood potassium (very common), and worsening kidney function and can be fatal. At first signs of increased frequency of bowel movements, contact your doctor immediately, drink plenty of fluids, and start antidiarrhoea treatment as soon as possible. You should have an anti-diarrhoeal medicine available before you start taking Vizimpro.
- Skin rash (very common)
It is important to treat the rash early. Tell your doctor if a rash starts. If treatment for rash is not working or the rash is getting worse (for example, you have peeling or cracking of the skin) you should tell your doctor immediately, since your doctor may decide to stop your treatment with Vizimpro. Rash may occur or worsen in areas exposed to sun. Sun protection with protective clothing and sunscreen is recommended.

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

Very common (may affect more than 1 in 10 people):

- Inflammation of the mouth and lips
- Nail problems
- Dry skin
- Loss of appetite
- Dry, red, or itchy eyes
- Weight loss
- Hair loss

- Itching
- Abnormal liver enzyme blood tests
- Nausea or vomiting
- Flushed or painful palms or soles
- Tiredness
- Weakness
- Cracks in the skin

Common (may affect up to 1 in 10 people):

- Alteration in taste
- Peeling skin
- Eyes inflammation
- Abnormal amount of body hair growth

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vizimpro

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

This medicine may pose a risk for the environment. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Vizimpro contains

- The active substance is dacomitinib (as dacomitinib monohydrate). Vizimpro film-coated tablets come in different strengths.
Vizimpro 15 mg tablet: each film-coated tablet contains 15 mg dacomitinib
Vizimpro 30 mg tablet: each film-coated tablet contains 30 mg dacomitinib
Vizimpro 45 mg tablet: each film-coated tablet contains 45 mg dacomitinib
- The other ingredients are:
Tablet core: lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, magnesium stearate (see section 2 *Vizimpro contains lactose and sodium*).
Film coating: Opadry II Blue 85F30716 containing polyvinyl alcohol – partially hydrolysed (E1203), talc (E553b), titanium dioxide (E171), macrogol (E1521), Indigo carmine aluminium lake (E132).

What Vizimpro looks like and contents of the pack

- Vizimpro 15 mg film-coated tablets are supplied as blue film-coated, round biconvex tablets, debossed with “Pfizer” on one side and “DCB15” on the other.

- Vizimpro 30 mg film-coated tablets are supplied as blue film-coated, round biconvex tablet, debossed with “Pfizer” on one side and “DCB30” on the other.
- Vizimpro 45 mg film-coated tablets are supplied as blue film-coated, round biconvex tablet, debossed with “Pfizer” on one side and “DCB45” on the other.

It is available in blister packs of 30 film-coated tablets.

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