

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr**VERZENIO**[®]

Abemaciclib Tablets

Read this carefully before you start taking VERZENIO 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 VERZENIO.

Your early or advanced breast cancer may be treated with VERZENIO in combination with another drug. Read the patient leaflet for the other drug as well as this one.

Serious Warnings and Precautions

Only a doctor who has experience treating cancer should treat you with this drug.

Venous Thromboembolism:

Venous thromboembolism refers to a blood clot. Blood clots can happen in any vein. Together they are called **Venous Thromboembolism**. In some patients it can lead to death.

Venous thromboembolism includes:

- deep vein thrombosis (DVT): blood clot in a large vein
- pulmonary embolism: blood clot in the lung
- pelvic venous thrombosis: blood clot in the pelvis
- cerebral venous thrombosis: blood clot in the brain
- blood clots in other veins such as in the abdomen, armpit, or on the way to the heart

Your healthcare professional might temporarily stop your dose of VERZENIO if you develop blood clots during treatment. The symptoms are listed in the table “Serious side effects and what to do about them”. It is found later in this leaflet.

What is VERZENIO used for?

VERZENIO is used to treat the different types of breast cancer in adults. The breast cancer has to be hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative. The types of breast cancer that VERZENIO treats are:

- Early breast cancer in adult women and men after completion of breast cancer surgery and related treatments. The cancer is lymph node positive and has a high chance of coming back. VERZENIO is taken:
 - with another treatment for breast cancer called hormone therapy.
- Advanced breast cancer in adult women, when it has spread to other parts of the body (metastatic). VERZENIO is taken:

- with another drug for breast cancer called an aromatase inhibitor. You must have already gone through menopause to take VERZENIO with an aromatase inhibitor. This is an initial therapy.

Or

- with another drug for breast cancer called fulvestrant. This is used when the cancer gets worse after initial therapy. If you have not yet gone through menopause, you must also take a medicine that will stop your ovaries from making estrogen.

Or

- by itself. You must have breast cancer that came back after having had hormone therapy and at least two kinds of prior chemotherapy treatment.

How does VERZENIO work?

Abemaciclib is a type of drug called a kinase inhibitor. It works by stopping cancer cells from dividing and growing. This may slow the growth and spread of breast cancer cells. It is given by itself, or together with other drugs (aromatase inhibitor, tamoxifen, or fulvestrant).

What are the ingredients in VERZENIO?

Medicinal ingredients: abemaciclib

Non-medicinal ingredients: croscarmellose sodium, lactose monohydrate, microcrystalline cellulose 101, microcrystalline cellulose 102, polyethylene glycol, polyvinyl alcohol, silicon dioxide, sodium stearyl fumarate, talc, titanium dioxide

Also contains:

50 mg and 200 mg tablets: iron oxide red, iron oxide yellow

150 mg tablet: iron oxide yellow

VERZENIO comes in the following dosage forms:

Tablets: 50 mg, 100 mg, 150 mg, and 200 mg

Do not use VERZENIO if:

- You are allergic to abemaciclib or any of the other ingredients of VERZENIO.

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

- Have fever, chills, or any other signs of an infection
- Have liver or kidney problems
- Are pregnant or plan to become pregnant
- Are breast-feeding
- Are over 65 years old

Other warnings you should know about:

Pregnancy, breast-feeding, and fertility

Avoid getting pregnant while receiving this medicine and for at least 3 weeks after the last dose of VERZENIO. If you have not gone through menopause, you should have a pregnancy test

done before you start treatment with VERZENIO. Talk to your healthcare professional about the best birth control for you. VERZENIO may cause harm to your unborn child. If you become pregnant, inform your doctor right away. Do not breast-feed your baby during treatment with VERZENIO and for at least 3 weeks after the last dose.

Sexual Health Male Patients

Before starting on VERZENIO you should know that it may affect your fertility. This may affect your ability to father a child. Talk to your healthcare professional if this is a concern for you.

Low white blood cell counts (neutropenia)

Low white blood cell counts are common while taking VERZENIO. They may cause serious infections that can cause death.

Infections

Serious infections can occur while taking VERZENIO. They may cause death.

Liver problems

VERZENIO can cause serious liver problems.

Diarrhea

VERZENIO can cause diarrhea. It may be severe at times. The most common time to start having diarrhea is during the first month of treatment. If you start having diarrhea, your healthcare professional may tell you to stop taking VERZENIO for a short time, decrease your dose, or stop your treatment. Cases of diarrhea have occurred with dehydration or an infection.

- **If you have any loose or liquid stools**, tell your healthcare professional right away. Start taking an antidiarrheal medicine (such as loperamide) and drink more fluids.

Blood clots in your arteries

Taking VERZENIO in combination with endocrine therapies for treatment of metastatic breast cancer may lead to serious blood clots. These blood clots can cause heart attack or stroke. It is not known if these blood clots occurred due to VERZENIO alone.

Lung problems (pneumonitis)

VERZENIO can cause severe inflammation of the lungs during treatment that can lead to death. Tell your healthcare professional right away if you have any new or worsening symptoms, including trouble breathing or shortness of breath, cough with or without mucus, or chest pain. If you develop lung problems during treatment with VERZENIO, your healthcare professional may tell you to temporarily stop taking VERZENIO, decrease your dose, or stop your treatment.

Children and adolescents

VERZENIO should not be given to patients under the age of 18 years.

Driving and Using Machines: Fatigue and dizziness can occur with VERZENIO. Before you do this wait until you know how you respond.

Check-ups and testing: You will have regular visits with your healthcare professional, before, during, or at the end of your treatment. They will check for signs and symptoms of:

- Lung problems
- Infections
- Blood clots
- Blood and liver problems by doing blood tests

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines.

Keep a list of the medicines you are taking. Show your healthcare professional or pharmacist when you get a new medicine.

The following may interact with VERZENIO:

- Some medicines for fungal infections, such as ketoconazole, itraconazole, posaconazole, and voriconazole
- Some medicines for infections (antibiotics), such as clarithromycin, ciprofloxacin, and rifampin
- Some medicines for high blood pressure, such as verapamil and diltiazem
- HIV medicines, such as saquinavir, ritonavir, and nelfinavir
- Medicines to treat epilepsy, such as carbamazepine and phenytoin
- The diabetes medicine metformin
- Some medicines for acid reflux such as ranitidine
- Medicines used to treat congestive heart failure and abnormal heart rhythms, such as digoxin
- St. John's wort, an herbal product used to treat depression and other conditions (also known as *hypericum perforatum*)
- Do not eat grapefruit or drink grapefruit juice while on VERZENIO. This includes any products with grapefruit. Grapefruit may increase the amount of VERZENIO in your blood.

Other drugs not listed here may also interact.

How to take VERZENIO:

- Take exactly as your healthcare provider tells you.
- Take with or without food.
- Swallow tablets whole.
 - Do NOT chew, crush, or split the tablets.
 - Do NOT take damaged tablets.
- Take doses at approximately the same time every day.
- If you vomit after taking a dose, take your next dose at your regular time.
- Your healthcare professional may decide to delay, stop, interrupt, decrease, or reduce your dose. This may occur if you get side effects.
- Take VERZENIO for as long as your healthcare professional recommends.

Usual dose:

Early Breast Cancer

Adult dose for women and men:

- When VERZENIO is taken with another drug or treatment for breast cancer: 150 mg two times a day (total of 300 mg a day).
- The smallest dose is: 50 mg two times a day.

Advanced or Metastatic Breast Cancer

Adult dose for women:

- When VERZENIO **is taken with another drug or treatment for breast cancer:** 150 mg two times a day (total of 300 mg a day).
- When VERZENIO **is taken by itself:** 200 mg two times a day (total of 400 mg a day).
- The smallest dose is: 50 mg two times a day.

Your healthcare professional will monitor your health. If you start having side effects, you may be told to delay or stop taking VERZENIO for a short time. Or, you may need to decrease your dose, or stop your treatment.

Overdose:

If you think you, or a person you are caring for, have taken too much VERZENIO, contact a 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 VERZENIO, take your next dose at your regular time. Do not take 2 doses of VERZENIO at the same time.

What are possible side effects from using VERZENIO?

These are not all the possible side effects you may have when taking VERZENIO. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Diarrhea, nausea, vomiting, decreased appetite, bloating, abdominal pain
- Headache, dizziness, sense of spinning
- Hair loss or thinning
- Feel faint or light-headed
- Tiredness, fatigue, muscle weakness
- Fracture or break a bone
- Rash, dry, itchy, infected or darkened or painful skin, bruising
- Ongoing itchy inflammation of the skin, inflamed fat layer below the skin
- Palmar-plantar erythrodysesthesia syndrome: pain, swelling, numbness, tingling, redness, and sometimes flaking or blistering of the palms or soles
- Increased tears
- Eye pain and blurred vision
- Changes to your sense of taste, dry mouth, sores in mouth, difficulty swallowing

If you have not gone through menopause, you should have a pregnancy test before you start VERZENIO.

VERZENIO can cause abnormal blood test results. This includes increased creatinine and liver enzymes. Your healthcare professional will test your blood before you start on VERZENIO. They will then test it every 2 weeks for the first two months. Then once a month for two months and whenever they think it is needed. Your healthcare professional will tell you if your test results are abnormal and if you need treatment to correct these side effects.

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			
Leukopenia, neutropenia, lymphopenia (Low white blood cells): Chills, fever, infection. Fatigue, aches and pains, and flu-like symptoms.		✓	
Anemia (Low red blood cells): Being short of breath, feeling very tired, loss of energy, weakness.		✓	
Thrombocytopenia (Low blood platelets): Bruising or bleeding for longer than usual if you hurt yourself. Fatigue, weakness.		✓	
Liver Problems: Feeling very tired with loss of appetite, pain on the upper right side of your stomach area (abdomen).		✓	
Diarrhea: At the first sign of loose or liquid stools.		✓	
COMMON			
Venous Thromboembolism (Blood clots in veins): Swelling, redness and pain in one part of the body, arms, or legs. This can be warm to touch. Sudden chest pain, rapid breathing and heart rate, shortness of breath. (Blood clots in the brain): Severe headache, feel numb, weak or cannot move arms, legs, or face, difficulty talking or seeing, fainting, or passing out, confusion, dizziness, blurred vision, or seizure (fit).		✓	
Infections: Upper Respiratory Tract (a cold): Chills, cough, fever, runny nose, shortness of breath, or sore throat. Urinary Tract: pain or burning sensation while urinating, frequent urination, blood in urine, pain in the pelvis, strong smelling urine, cloudy urine		✓	
Hypokalemia (Decreased potassium in the blood): Irregular heartbeats, muscle weakness and generally feeling unwell.		✓	
Hypocalcemia (Low Level of Calcium in the Blood): Muscle cramps in the back and legs. Dry skin. Confusion and memory loss.		✓	
Pneumonia (Infection in the lungs), Pneumonitis (Lung inflammation), or		✓	

Pulmonary Fibrosis: New or worsening shortness of breath, cough, wheezing or fever. Difficult and painful breathing. Feel tired.			
Heart Problems (Tachycardia, atrial fibrillation, palpitations, heart failure): Fast or irregular heartbeat, chest pain, heart racing or skips a beat, short of breath, fatigue, inability to exercise, and fluid in the legs.		✓	
Kidney Problems (Inability of the kidneys to properly clean the blood): A change in the amount of urine you pass. Water retention with weight gain swelling of legs and ankles, puffy face or hands. Lack of appetite, nausea, vomiting, weakness. Itchy skin. Decreased concentration. Flank or lower back pain.		✓	
Sepsis (Blood infection that is body wide): High fever, fast heart rate, and breathing.		✓	
UNKNOWN FREQUENCY			
Allergic Reactions: Itch, rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing.			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell 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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) 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 at room temperature between 15°C to 30°C.

Keep out of reach and sight of children.

If you want more information about VERZENIO:

- 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:

(<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.lilly.ca, or by calling 1-888-545-5972.

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