

PATIENT INFORMATION
VERZENIO® (ver-ZEN-ee-oh)
(abemaciclib)
tablets

What is the most important information I should know about VERZENIO?

VERZENIO may cause serious side effects including:

- **Diarrhea.** Diarrhea is common with VERZENIO treatment and may sometimes be severe. Diarrhea may cause you to develop dehydration or an infection. The most common time to develop diarrhea is during the first month of VERZENIO treatment. If you develop diarrhea during treatment with VERZENIO, your healthcare provider may tell you to temporarily stop taking VERZENIO, stop your treatment, or decrease your dose.
 - **If you have any loose stools,** start taking an antidiarrheal medicine (such as loperamide), drink more fluids, and tell your healthcare provider right away.
- **Low white blood cell counts (neutropenia).** Low white blood cell counts are common during treatment with VERZENIO and may cause serious infections that can lead to death. Your healthcare provider should check your white blood cell counts before and during treatment. If you develop low white blood cell counts during treatment with VERZENIO, your healthcare provider may tell you to temporarily stop taking VERZENIO, decrease your dose, or wait before starting your next month of treatment. **Tell your healthcare provider right away if you have signs and symptoms of low white blood cell counts or infections, such as fever and chills.**
- **Lung problems.** VERZENIO may cause severe or life-threatening inflammation of the lungs during treatment that can lead to death. If you develop lung problems during treatment with VERZENIO, your healthcare provider may tell you to temporarily stop taking VERZENIO, decrease your dose, or stop your treatment. Tell your healthcare provider right away if you have any new or worsening symptoms, including:
 - trouble breathing or shortness of breath
 - cough with or without mucus
 - chest pain
- **Liver problems.** VERZENIO can cause serious liver problems. Your healthcare provider should do blood tests to check your liver before and during treatment with VERZENIO. If you develop liver problems during treatment with VERZENIO, your healthcare provider may reduce your dose or stop your treatment. Tell your healthcare provider right away if you have any of the following signs and symptoms of liver problems:
 - feeling very tired
 - pain on the upper right side of your stomach area (abdomen)
 - loss of appetite
 - bleeding or bruising more easily than normal
- **Blood clots in your veins, or in the arteries of your lungs.** VERZENIO may cause serious blood clots that have led to death. If you develop blood clots during treatment with VERZENIO, your healthcare provider may tell you to temporarily stop taking VERZENIO. Tell your healthcare provider right away if you get any of the following signs and symptoms of a blood clot:
 - pain or swelling in your arms or legs
 - shortness of breath
 - chest pain
 - rapid breathing
 - rapid heart rate

See “What are the possible side effects of VERZENIO?” for more information about side effects.

What is VERZENIO?

VERZENIO is a prescription medicine used:

- in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) to treat adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer with a high risk of coming back as determined by your healthcare provider.
- in combination with an aromatase inhibitor as the first endocrine-based therapy to treat adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer that has worsened or that has spread to other parts of the body (metastatic).
- in combination with fulvestrant to treat adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer that has worsened or spread to other parts of the body (metastatic) and whose disease has progressed after endocrine therapy.
- alone to treat adults with HR-positive, HER2-negative breast cancer that has worsened or that has spread to other parts of the body (metastatic) and whose disease has progressed after endocrine therapy and prior chemotherapy.

When VERZENIO is used in combination with fulvestrant, tamoxifen, or an aromatase inhibitor, also read the Patient Information for the prescribed product. Ask your healthcare provider if you are not sure.

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

Before taking VERZENIO, tell your healthcare provider about all of your medical conditions, including if you:

- have fever, chills, or any other signs of an infection.
- have a history of blood clots in your veins.
- have lung or breathing problems.
- have liver or kidney problems.
- are pregnant or plan to become pregnant. VERZENIO can harm your unborn baby.

Females who are able to become pregnant:

- Your healthcare provider will do a pregnancy test before you start treatment with VERZENIO.
- You should use effective birth control (contraception) during treatment with VERZENIO and for 3 weeks after the last dose of VERZENIO.
- Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with VERZENIO.
- are breastfeeding or plan to breastfeed. It is not known if VERZENIO passes into your breast milk. Do not breastfeed during treatment with VERZENIO and for at least 3 weeks after the last dose of VERZENIO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. VERZENIO may affect the way other medicines work, and other medicines may affect how VERZENIO works, causing serious side effects.

Especially tell your healthcare provider if you take a medicine that contains ketoconazole.

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

How should I take VERZENIO?

- Take VERZENIO exactly as your healthcare provider tells you.
- Your healthcare provider may change your dose if needed. Do not stop taking VERZENIO or change the dose without talking to your healthcare provider.
- VERZENIO may be taken with or without food.
- Swallow VERZENIO tablets whole. Do not chew, crush, or split the tablets before swallowing. Do not take VERZENIO tablets if they are broken, cracked, or damaged.
- Take your doses of VERZENIO at about the same time every day.
- If you vomit or miss a dose of VERZENIO, take your next dose at your regular time. Do not take 2 doses of VERZENIO at the same time to make up for the missed dose.

What should I avoid during treatment with VERZENIO?

- Avoid taking ketoconazole during treatment with VERZENIO. Tell your healthcare provider if you take a medicine that contains ketoconazole.
- Avoid grapefruit and products that contain grapefruit during treatment with VERZENIO. Grapefruit may increase the amount of VERZENIO in your blood.

What are the possible side effects of VERZENIO?

VERZENIO may cause serious side effects, including:

- See “What is the most important information I should know about VERZENIO?”

The most common side effects of VERZENIO include:

- nausea
- infections
- low red blood cell counts (anemia)
- decreased appetite
- headache
- hair thinning or hair loss (alopecia)
- abdominal pain
- tiredness
- low white blood cell counts (leukopenia)
- vomiting
- low platelet count (thrombocytopenia)

VERZENIO may cause fertility problems in males. This may affect your ability to father a child. Talk to your healthcare provider if this is a concern for you.

These are not all the possible side effects of VERZENIO. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store VERZENIO?

- Store VERZENIO at room temperature between 68°F to 77°F (20°C to 25°C).

Keep VERZENIO and all medicines out of the reach of children.

General information about the safe and effective use of VERZENIO.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use VERZENIO for a condition for which it was not prescribed. Do not give VERZENIO to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for more information about VERZENIO that is written for health professionals.

What are the ingredients in VERZENIO?

Active ingredient: abemaciclib

Inactive ingredients: microcrystalline cellulose 102, microcrystalline cellulose 101, lactose monohydrate, croscarmellose sodium, sodium stearyl fumarate, silicon dioxide.

Color mixture ingredients: polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, iron oxide yellow, iron oxide red.

Marketed by: Lilly USA, LLC, Indianapolis, IN 46285, USA

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For more information, go to www.verzenio.com or call 1-800-545-5979.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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